

SUBMITTAL TO THE RIVERSIDE UNIVERSITY HEALTH SYSTEM MEDICAL CENTER GOVERNING BOARD COUNTY OF RIVERSIDE, STATE OF CALIFORNIA



1TEM 15:1

(ID # 9595)

MEETING DATE:

Tuesday, April 30, 2019

FROM: RUHS-MEDICAL CENTER:

SUBJECT: RIVERSIDE UNIVERSITY HEALTH SYSTEM - MEDICAL CENTER: Approval of the Professional Services Agreement with the Blood Bank of San Bernardino and Riverside Counties dba Lifestream for Blood Product and Therapeutic Apheresis Services; District- All [\$2,750,000 annual; total cost \$15,010,000; up to \$275,000 in additional compensation per fiscal year] - 100% Hospital Enterprise Fund]

RECOMMENDED MOTION: That the Governing Board:

- Approve the Professional Services Agreement with the Blood Bank of San Bernardino and Riverside Counties dba Lifestream in the amount not to exceed \$2,750,000 annually for Blood Product and Therapeutic Apheresis Services from execution through December 31, 2024, and authorize the Chairman of the Board to execute the same on behalf of the County; and
- 2. Authorize the Purchasing Agent, in accordance Ordnance No. 459 based on the availability of fiscal funding and in a form approved by County Counsel to: a) sign amendments that do not change the substantive terms of the Agreement and b) sign amendments to the compensation provisions that do not exceed the sum total of ten percent (10%) of the total annual cost of the contract.

ACTION:Policy

MINUTES OF THE GOVERNING BOARD

On motion of Supervisor Jeffries, seconded by Supervisor Perez and duly carried, IT WAS ORDERED that the above matter is approved as recommended.

Ayes:

Jeffries, Spiegel, Washington and Perez

Navs:

None

Absent:

Hewitt

Date:

April 30, 2019

XC:

RUHS-Medical Center, Purchasing

Kecia Harper

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

FINANCIAL DATA	Curr	ent Fiscal Year:	Ne	xt Fiscal Year:	Total Cost:	Ongoing Cost	
COST	\$	1,260,000	\$	2,750,000	\$ 15,010,000	\$	2,750,000
NET COUNTY COST		\$0		\$0	\$0		\$ 0
SOURCE OF FUNDS	Budget Adjustment: No						
					For Fiscal Ye	ear:	18/19-
					24/25		

C.E.O. RECOMMENDATION: Approve

BACKGROUND:

Summary

Riverside University Health System Medical Center (RUHS-MC) has contracted with Blood Bank of San Bernardino and Riverside Counties d/b/a LIFESTREAM (LIFESTREAM) to provide blood product & blood-related services since 1991 and for the Therapeutic Apheresis program since 1999. Historically, LIFESTREAM has been the sole provider able to supply these needed services for the hospital. On August 31, 2010, Agenda Item # 3.70, the Board approved the professional services agreement with LIFESTREAM to continue services with renegotiated rates for the blood product and blood related services and Therapeutic Apheresis program; this agreement expired in 2013. At this time, RUHS-MC desires to enter into a new agreement with LIFESTREAM for said services.

LIFESTREAM is located in San Bernardino; they are geographically able to provide immediate response time and support for RUHS-MC. As the consummate provider within the Inland Empire, they have experience working with other comparable size hospital facilities, in turn; they are capable of providing an abundant supply of blood products to RUHS-MC and other surrounding hospitals.

Because very few vendors offer these specific services within Riverside County's geographic area, and transporting blood products from another county would not be cost efficient or practical, RUHS-MC requests the Board approve the multi-year Agreement with Blood Bank of San Bernardino/Riverside Counties d/b/a LIFESTREAM.

Impact on Residents and Businesses

The approval of this Agreement will have a positive impact on the citizens and businesses of Riverside County as life-saving blood products will be readily available for emergencies, traumas and surgeries at RUHS-MC.

Additional Fiscal Information

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

Description:	4/30/2019 - 12/31/2019	1/1/2020 - 12/31/2020	1/1/2021 – 12/31/2021	1/1/2022 – 12/31/2022	1/1/23 – 12/31/2023	1/1/2024 – 12/31/2024	Total
Ongoing Costs:	\$1,260,000	\$2,750,000	\$2,750,000	\$2,750,000	\$2,750,000	\$2,750,000	\$15,010,000
Total Costs	\$1,260,000	\$2,750,000	\$2,750,000	\$2,750,000	\$2,750,000	\$2,750,000	\$15,010,000

Contract History and Price Reasonableness

Lifestream is located in San Bernardino and they are most capable and able to transport blood product and services directly to the hospital, providing immediate response time and support for RUHS-MC patients. No other vendor in the geographical area offers these specific services. Transporting blood products from another county would not be cost effective or practical for Riverside County. Blood Bank of San Bernardino and Riverside Counties d/b/a/ LIFESTREAM certifies that prices offered are the lowest or equal to any comparable customer based on RUHS-MC usage over the last three years, and are equivalent to the fee schedules offered to Federal, State, or Local Governments, based upon negotiated State or Local contracts.

Teresa Summers, Director of Purchasing 4/22/2019 Melissa Noone, Associate Management Analyst 4/23/2019

Gregory V. Prianos, Director County Counsel 4/23/2019



Dat	te:	April 4, 2019				
Fro	em:	Jennifer Cruikchank,	Chief Executive Officer, RUHS			
To:		Board of Supervisors	s/Purchasing Agent			
Via	:	RUHS Admin., Greg	Prouty, Executive Director, Support Services 951-486-7503			
	oject: unties d/b /	Single Source Procu a/ LIFESTREAM	rement; Blood Bank of San Bernardino and Riverside			
1.	Supplier be		d Bank of San Bernardino and Riverside Counties d/b/a			
2.	Vendor ID:	77851				
3.	■ Single	Source [□ Sole Source			
4 . l		reviously requested a r for your department	and received approval for a sole or single source request for ?			
	□Yes	1	■ No			
4a.	Was the re	equest approved for	r a different project?			
	□Yes	•	■ No			
4.	4. Supply/Service being requested: Blood product & blood related services and Therapeutic Apheresis for RUHS-MC emergency and surgical patients. This request would fall under BOS Approval Resolution 2017-18 for direct patient care; however, the annual cost for the agreement exceeds \$750,000.					
6.	Unique features of the supply/service being requested from this supplier. Lifestream is located in San Bernardino and they are most capable and able to transport blood product and services directly to the hospital, providing immediate response time and support for RUHS-MC patients.					
7.	benefit will specific s	accrue to the county	equires these unique features from the vendor and what read to be not be read to be read			
8.	Period of F	Performance: May 1,	2019 to December 31, 2023 (5 Years)			



Is this an annually renewable contract?	□ No	■ Yes
Is this a fixed-term agreement:	□ No	☐ Yes

9. Identify all costs for this requested purchase.

Description:	FY19	FY_20	FY21	FY22	FY23	Total
Ongoing Costs:	\$1,375,000	\$2,750,000	\$2,750,000	\$2,750,000	\$2,750,000	\$12,375,000
Total Costs	\$1,375,000	\$2,750,000	\$2,750,000	\$2,750,000	\$2,750,000	\$12,375,000

- 10. Price Reasonableness: Blood Bank of San Bernardino and Riverside Counties d/b/a/ LIFESTREAM certifies that prices offered are the lowest or equal to any comparable customer based on RUHS-MC usage over the last three years, and are equivalent to the fee schedules offered to Federal, State, or Local Government based upon negotiated State or Local contracts.
- 11. Projected Board of Supervisor Date: April 30, 2019

	Jennifer Cruikchank	
Department Head Signature	Print Name	Date



The section below is to be completed by the Purchasing Agent or designee.					
Purchasing Department C	comments:				
Approve	Approve	with Condition/s	Disapprove		
Condition/s:					
Not to exceed:					
□ One-time	\$				
☐ Annual A	mount \$ Annual Amount Varie	/ per fiscal year throughes each FY)	n(date)		
	: \$				
	: \$				
FY	: \$				
	: \$				
	: \$				
Purchasing Agent	Date	Approval Nu (Reference on Purchas			

PROFESSIONAL SERVICE AGREEMENT

for

BLOOD PRODUCT AND THERAPEUTIC APHERESIS SERVICES

between

COUNTY OF RIVERSIDE

and

BLOOD BANK OF SAN BERNARDINO AND RIVERSIDE COUNTIES d/b/a LIFESTREAM



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This Agreement, made and entered into this _____day of ______, 2019, by and between BLOOD BANK OF SAN BERNARDINO AND RIVERSIDE COUNTIES a California nonprofit corporation doing business as LIFESTREAM, (herein referred to as "CONTRACTOR"), and the COUNTY OF RIVERSIDE, a political subdivision of the State of California, (herein referred to as "COUNTY"). The parties agree as follows:

1. <u>Description of Services</u>

- 1.1 CONTRACTOR shall provide all services as outlined and specified in Exhibit A-1 and A-2, Scope of Services, at the prices stated in Exhibit B, Payment Provisions, and Attachment I, HIPAA Business Associate Attachment to the Agreement.
- 1.2 CONTRACTOR represents that it has the skills, experience, and knowledge necessary to perform under this Agreement and the COUNTY relies upon this representation. CONTRACTOR shall perform to the satisfaction of the COUNTY and in conformance to and consistent with the highest standards of firms/professionals in the same discipline in the State of California. COUNTY shall utilize CONTRACTOR as its exclusive provider of the services described in this Agreement.
- 1.3 CONTRACTOR affirms this it is fully apprised of all of the work to be performed under this Agreement; and the CONTRACTOR agrees it can properly perform this work at the prices stated in Exhibit B. CONTRACTOR is not to perform services or provide products outside of the Agreement.
- 1.4 Acceptance by the COUNTY of the CONTRACTOR's performance under this Agreement does not operate as a release of CONTRACTOR's responsibility for full compliance with the terms of this Agreement.

2. Period of Performance

2.1 This Agreement shall be effective upon signature of this Agreement by both parties and continues in effect through December 31, 2024, unless terminated earlier. CONTRACTOR shall commence performance upon signature of this Agreement by both parties and shall diligently and continuously perform thereafter. The Riverside County Board of Supervisors is the only authority that may obligate the County for a non-cancelable multi-year agreement.

3. Compensation

3.1 The COUNTY shall pay the CONTRACTOR for services performed, products provided and expenses incurred in accordance with the terms of Exhibit B, Payment Provisions. Maximum payments by COUNTY to CONTRACTOR under this Agreement shall not exceed \$2,750,000.00 annually including all expenses. The COUNTY is not responsible for any fees or costs incurred above or beyond the contracted

amount and shall have no obligation to purchase any specified amount of services or products, but shall not purchase these services from another provider during the term of this agreement, except in instances where CONTACTOR is unable to provide these services in a timely manner. Unless otherwise specifically stated in Exhibit B, COUNTY shall not be responsible for payment of any of CONTRACTOR's expenses related to this Agreement.

- 3.2 No price increases will be permitted during the first year of this Agreement (If applicable). All price decreases (for example, if CONTRACTOR offers lower prices to another governmental entity) will automatically be extended to the COUNTY. The COUNTY requires written proof satisfactory to COUNTY of cost increases prior to any approved price adjustment. After the first year of the award, a minimum of 30-days advance notice in writing is required to be considered and approved by COUNTY. No retroactive price adjustments will be considered. Any price increases must be stated in a written amendment to this Agreement. The net dollar amount of profit will remain firm during the period of the Agreement. Annual increases shall not exceed the Consumer Price Index- All Consumers, All Items Greater Los Angeles, Riverside and Orange County areas and be subject to satisfactory performance review by the COUNTY and approved (if needed) for budget funding by the Board of Supervisors.
- 3.3 CONTRACTOR shall be paid only in accordance with an invoice submitted to COUNTY by CONTRACTOR within fifteen (15) days from the last day of each calendar month, and COUNTY shall pay the invoice within thirty (30) working days from the date of receipt of the invoice. Payment shall be made to CONTRACTOR only after services have been rendered or delivery of materials or products, and acceptance has been made by COUNTY. Prepare invoices in duplicate. For this Agreement, send the original and duplicate copies of invoices to:

Riverside County Regional Medical Center

Accounts Payable

26520 Cactus Avenue Moreno Valley, CA 92555

- a) Each invoice shall contain a minimum of the following information: invoice number and date; remittance address; bill-to and ship-to addresses of ordering department/division; Agreement number MCARC-27114-004-12/23 quantities; item descriptions, unit prices, extensions, sales/use tax if applicable, and an invoice total.
- b) Invoices shall be rendered bi-monthly in arrears.
- 3.4 The COUNTY obligation for payment of this Agreement beyond the current fiscal year end is contingent upon and limited by the availability of COUNTY funding from which payment can be made.

In the State of California, Government agencies are not allowed to pay excess interest and late charges, per Government Code, Section 926.10. No legal liability on the part of the COUNTY shall arise for payment beyond June 30 of each calendar year unless funds are made available for such payment. In the event that such funds are not forthcoming for any reason, COUNTY shall immediately notify CONTRACTOR in writing; and this Agreement shall be deemed terminated, have no further force, and effect.

4. Alteration or Changes to the Agreement

- 4.1 The Board of Supervisors and the COUNTY Purchasing Agent and/or his designee is the only authorized COUNTY representatives who may at any time, by written order, alter this Agreement. If any such alteration causes an increase or decrease in the cost of, or the time required for the performance under this Agreement, an equitable adjustment shall be made in the Agreement price or delivery schedule, or both, and the Agreement shall be modified by written amendment accordingly.
- 4.2 Any claim by the CONTRACTOR for additional payment related to this Agreement shall be made in writing by the CONTRACTOR within 30 days of when the CONTRACTOR has or should have notice of any actual or claimed change in the work, which results in additional and unanticipated cost to the CONTRACTOR. If the COUNTY Purchasing Agent decides that the facts provide sufficient justification, he may authorize additional payment to the CONTRACTOR pursuant to the claim. Nothing in this section shall excuse the CONTRACTOR from proceeding with performance of the Agreement even if there has been a change.

5. Termination

- **5.1**. COUNTY may terminate this Agreement without cause upon 180 days written notice served upon the CONTRACTOR stating the extent and effective date of termination.
- **5.2** COUNTY may, upon five (5) days written notice terminate this Agreement for CONTRACTOR's default, if CONTRACTOR refuses or fails to comply with the terms of this Agreement or fails to make progress that may endanger performance and does not immediately cure such failure. In the event of such termination, the COUNTY may proceed with the work in any manner deemed proper by COUNTY.
 - 5.3 After receipt of the notice of termination, CONTRACTOR shall:
 - (a) Stop all work under this Agreement on the date specified in the notice of termination; and

- (b) Transfer to COUNTY and deliver in the manner as directed by COUNTY any materials, reports or other products, which, if the Agreement had been completed or continued, would have been required to be furnished to COUNTY.
- 5.4 After termination, COUNTY shall make payment only for CONTRACTOR's performance up to the date of termination in accordance with this Agreement.
- 5.5 CONTRACTOR's rights under this Agreement shall terminate (except for fees accrued prior to the date of termination) upon dishonesty or a willful or material breach of this Agreement by CONTRACTOR; or in the event of CONTRACTOR's unwillingness or inability for any reason whatsoever to perform the terms of this Agreement. In such event, CONTRACTOR shall not be entitled to any further compensation under this Agreement.
- 5.6 If the Agreement is federally or State funded, CONTRACTOR cannot be debarred from the System for Award Management (SAM). CONTRACTOR must notify the COUNTY immediately of a debarment. Reference: System for Award Management (SAM) at https://www.sam.gov for Central Contractor Registry (CCR), Federal Agency Registration (Fedreg), Online Representations and Certifications Application, and Excluded Parties List System (EPLS)). Excluded Parties Listing System (EPLS) (http://www.epls.gov) (Executive Order 12549, 7 CFR Part 3017, 45 CFR Part 76, and 44 CFR Part 17). The System for Award Management (SAM) is the Official U.S. Government system that consolidated the capabilities of CCR/FedReg, ORCA, and EPLS.
- 5.7 The rights and remedies of COUNTY or CONTRACTOR provided in this section shall not be exclusive and are in addition to any other rights and remedies provided by law or this Agreement.

6. Ownership/Use of Contract Materials and Products

The CONTRACTOR agrees that all materials, reports or products in any form, including electronic, created by CONTRACTOR for which CONTRACTOR has been compensated by COUNTY pursuant to this Agreement shall be the sole property of the COUNTY. The material, reports or products may be used by the COUNTY for any purpose that the COUNTY deems to be appropriate, including, but not limit to, duplication and/or distribution within the COUNTY or to third parties. CONTRACTOR agrees not to release or circulate in whole or part such materials, reports, or products without prior written authorization of the COUNTY.

7. Conduct of Contractor

7.1 The CONTRACTOR covenants that it presently has no interest, including, but not limited to, other projects or contracts, and shall not acquire any such interest, direct or indirect, which would conflict in

any manner or degree with CONTRACTOR's performance under this Agreement. The CONTRACTOR further covenants that no person or subcontractor having any such interest shall be employed or retained by CONTRACTOR under this Agreement. The CONTRACTOR agrees to inform the COUNTY of all the CONTRACTOR's interests, if any, which are or may be perceived as incompatible with the COUNTY's interests.

- 7.2 The CONTRACTOR shall not, under circumstances which could be interpreted as an attempt to influence the recipient in the conduct of his/her duties, accept any gratuity or special favor from individuals or firms with whom the CONTRACTOR is doing business or proposing to do business, in accomplishing the work under this Agreement.
- 7.3 The CONTRACTOR or its employees shall not offer gifts, gratuity, favors, and entertainment directly or indirectly to COUNTY employees.

8. <u>Inspection of Service; Quality Control/Assurance</u>

- 8.1 All performance (which includes services, workmanship, materials, supplies and equipment furnished or utilized in the performance of this Agreement) shall be subject to inspection and test by the COUNTY or other regulatory agencies at all times. The CONTRACTOR shall provide adequate cooperation to any inspector or other COUNTY representative to permit him/her to determine the CONTRACTOR's conformity with the terms of this Agreement. If any services performed or products provided by CONTRACTOR are not in conformance with the terms of this Agreement, the COUNTY shall have the right to require the CONTRACTOR to perform the services or provide the products in conformance with the terms of the Agreement at no additional cost to the COUNTY. When the services to be performed or the products to be provided are of such nature that the difference cannot be corrected; the COUNTY shall have the right to: (1) require the CONTRACTOR immediately to take all necessary steps to ensure future performance in conformity with the terms of the Agreement; and/or (2) reduce the Agreement price to reflect the reduced value of the services performed or products provided. The COUNTY may also terminate this Agreement for default and charge to CONTRACTOR any costs incurred by the COUNTY because of the CONTRACTOR's failure to perform.
- **8.2** CONTRACTOR shall establish adequate procedures for self-monitoring and quality control and assurance to ensure proper performance under this Agreement; and shall permit a COUNTY representative or other regulatory official to monitor, assess, or evaluate CONTRACTOR's performance under this Agreement at any time, upon reasonable notice to the CONTRACTOR.

9. <u>Independent Contractor/Employment Eligibility</u>

- 9.1 The CONTRACTOR is, for purposes relating to this Agreement, an independent contractor and shall not be deemed an employee of the COUNTY. It is expressly understood and agreed that the CONTRACTOR (including its employees, agents, and subcontractors) shall in no event be entitled to any benefits to which COUNTY employees are entitled, including but not limited to overtime, any retirement benefits, worker's compensation benefits, and injury leave or other leave benefits. There shall be no employer-employee relationship between the parties; and CONTRACTOR shall hold COUNTY harmless from any and all claims that may be made against COUNTY based upon any contention by a third party that an employer-employee relationship exists by reason of this Agreement. It is further understood and agreed by the parties that CONTRACTOR in the performance of this Agreement is subject to the control or direction of COUNTY merely as to the results to be accomplished and not as to the means and methods for accomplishing the results.
- 9.2 CONTRACTOR warrants that it shall make its best effort to fully comply with all federal and state statutes and regulations regarding the employment of aliens and others and to ensure that employees performing work under this Agreement meet the citizenship or alien status requirement set forth in federal statutes and regulations. CONTRACTOR shall obtain, from all employees performing work hereunder, all verification and other documentation of employment eligibility status required by federal or state statutes and regulations including, but not limited to, the Immigration Reform and Control Act of 1986, 8 U.S.C. §1324 et seq., as they currently exist and as they may be hereafter amended. CONTRACTOR shall retain all such documentation for all covered employees, for the period prescribed by the law.
- 9.3 Ineligible Person shall be any individual or entity who: Is currently excluded, suspended, debarred or otherwise ineligible to participate in the federal health care programs; or has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.
- 9.4 CONTRACTOR shall screen prospective Covered Individuals prior to hire or engagement. CONTRACTOR shall not hire or engage any Ineligible Person to provide services directly relative to this Agreement. Covered Individuals shall be required to disclose to CONTRACTOR immediately any debarment, exclusion or other event that makes the Covered Individual an Ineligible Person. CONTRACTOR shall notify COUNTY within five (5) business days after it becomes aware if a Covered Individual providing services directly relative to this Agreement becomes debarred, excluded or otherwise becomes an Ineligible Person.

- 9.5 CONTRACTOR acknowledges that Ineligible Persons are precluded from providing federal and state funded health care services by contract with COUNTY in the event that they are currently sanctioned or excluded by a federal or state law enforcement regulatory or licensing agency. If CONTRACTOR becomes aware that a Covered Individual has become an Ineligible Person, CONTRACTOR shall remove such individual from responsibility for, or involvement with, COUNTY business operations related to this Agreement.
- 9.6 CONTRACTOR shall notify COUNTY within five (5) business days if a Covered Individual or entity is currently excluded, suspended or debarred, or is identified as such after being sanction screened. Such individual or entity shall be promptly removed from participating in any activity associated with this Agreement.

10. <u>Subcontract for Work or Services</u>

No contract shall be made by the CONTRACTOR with any other party for furnishing any of the work or services under this Agreement without the prior written approval of the COUNTY; but this provision shall not require the approval of contracts of employment between the CONTRACTOR and personnel assigned under this Agreement, or for parties named in the proposal and agreed to under this Agreement. COUNTY acknowledges and approves that therapeutic apheresis services to be provided under this Agreement are subcontracted to Apheresis Care Group/Fresenius Medical Services and that delivery services may from time to time be performed by subcontracted courier services, with the provision that CONTRACTOR shall require these subcontractors to adhere to all terms and conditions, including all insurance provisions per section 22E 6) in this Agreement.

11. <u>Disputes</u>

- 11.1 The parties shall attempt to resolve any disputes amicably at the working level. If that is not successful, the dispute shall be referred to the senior management of the parties. The CONTRACTOR shall proceed diligently with the performance of this Agreement pending the resolution of a dispute.
- 11.2 Prior to the filing of any legal action related to this Agreement, the parties shall be obligated to attend a mediation session in Riverside County before a neutral third-party mediator. A second mediation session shall be required if the first session is not successful. The parties shall share the cost of the mediations.

12. Licensing and Permits

CONTRACTOR shall comply with all State or other licensing requirements, including but not limited to the provisions of Chapter 9 of Division 3 of the Business and Professions Code. All licensing

SSI#

requirements shall be met at the time proposals are submitted to the COUNTY. CONTRACTOR warrants that it has all necessary permits, approvals, certificates, waivers and exemptions necessary for performance of this Agreement as required by the laws and regulations of the United States, the State of California, the County of Riverside and all other governmental agencies with jurisdiction, and shall maintain these throughout the term of this Agreement.

13. <u>Use By Other Political Entities</u>

The CONTRACTOR agrees to extend the same pricing, terms, and conditions as stated in this Agreement to each and every political entity, special district, and related non-profit entity in Riverside County. It is understood that other entities shall make purchases in their own name, make direct payment, and be liable directly to the CONTRACTOR; and COUNTY shall in no way be responsible to CONTRACTOR for other entities' purchases.

14. Non-Discrimination

CONTRACTOR shall not discriminate in the provision of services, allocation of benefits, accommodation in facilities, or employment of personnel on the basis of ethnic group identification, race, religious creed, color, national origin, ancestry, physical handicap, medical condition, marital status or sex in the performance of this Agreement; and, to the extent they shall be found to be applicable hereto, shall comply with the provisions of the California Fair Employment and Housing Act (Gov. Code 12900 et. seq), the Federal Civil Rights Act of 1964 (P.L. 88-352), the Americans with Disabilities Act of 1990 (42 U.S.C. S1210 et seq.) and all other applicable laws or regulations.

15. Records and Documents

COUNTY agency, a copy of this Agreement and such books, documents and records as are necessary to certify the nature and extent of the CONTRACTOR's costs related to this Agreement. All such books, documents and records shall be maintained by CONTRACTOR for at least five years following termination of this Agreement and be available for audit by the COUNTY. CONTRACTOR shall provide to the COUNTY reports and information related to this Agreement as requested by COUNTY.

16. Confidentiality

16.1 The CONTRACTOR shall not use for personal gain or make other improper use of privileged or confidential information which is acquired in connection with this Agreement. The term "privileged or confidential information" includes but is not limited to: unpublished or sensitive technological or scientific information; medical, personnel, or security records; anticipated material

requirements or pricing/purchasing actions; COUNTY information or data which is not subject to public disclosure; COUNTY operational procedures; and knowledge of selection of contractors, subcontractors or suppliers in advance of official announcement.

16.2 The CONTRACTOR shall protect from unauthorized disclosure names and other identifying information concerning persons receiving services pursuant to this Agreement, except for general statistical information not identifying any person. The CONTRACTOR shall not use such information for any purpose other than carrying out the CONTRACTOR's obligations under this Agreement. The CONTRACTOR shall promptly transmit to the COUNTY all third party requests for disclosure of such information. The CONTRACTOR shall not disclose, except as otherwise specifically permitted by this Agreement or authorized in advance in writing by the COUNTY, any such information to anyone other than the COUNTY. For purposes of this paragraph, identity shall include, but not be limited to, name, identifying number, symbol, or other identifying particulars assigned to the individual, such as finger or voice print or a photograph.

16.3 The CONTRACTOR is subject to and shall operate in compliance with all relevant requirements contained in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, enacted August 21, 1996, and the related laws and regulations promulgated subsequent thereto. Please refer to Attachment 1 of this Agreement.

17. Administration/Contract Liaison

The COUNTY Purchasing Agent, or designee, shall administer this Agreement on behalf of the COUNTY. The Purchasing Department is to serve as the liaison with CONTRACTOR in connection with this Agreement.

18. Notices

All correspondence and notices required or contemplated by this Agreement shall be delivered to the respective parties at the addresses set forth below and are deemed submitted two days after their deposit in the United States mail, postage prepaid:

COUNTY OF RIVERSIDE

Purchasing and Fleet Department 2980 Washington St Riverside, CA 92504

CONTRACTOR

LifeStream
P.O. Box 1429
San Bernardino, CA 92402-1429
Attn: Frederick B. Axelrod, M.D., MBA
President/CEO/Medical Director

19. Force Majeure

If either party is unable to comply with any provision of this Agreement due to causes beyond its reasonable control, and which could not have been reasonably anticipated, such as acts of God, acts of war, civil disorders, or other similar acts, such party shall not be held liable for such failure to comply.

20. EDD Reporting Requirements

In order to comply with child support enforcement requirements of the State of California, the COUNTY may be required to submit a Report of Independent Contractor(s) form **DE 542** to the Employment Development Department. The CONTRACTOR agrees to furnish the required data and certifications to the COUNTY within 10 days of notification of award of Agreement when required by the EDD. This data will be transmitted to governmental agencies charged with the establishment and enforcement of child support orders. Failure of the CONTRACTOR to timely submit the data and/or certificates required may result in the contract being awarded to another contractor. In the event a contract has been issued, failure of the CONTRACTOR to comply with all federal and state reporting requirements for child support enforcement or to comply with all lawfully served Wage and Earnings Assignments Orders and Notices of Assignment shall constitute a material breach of Agreement. If CONTRACTOR has any questions concerning this reporting requirement, please call (916) 657-0529. CONTRACTOR should also contact its local Employment Tax Customer Service Office listed in the telephone directory in the State Government section under "Employment Development Department" or access their Internet site at www.edd.ca.gov.

21. Hold Harmless/Indemnification

21.1 CONTRACTOR shall indemnify and hold harmless the County of Riverside, its Agencies, Districts, Special Districts and Departments, their respective directors, officers, Board of Supervisors, elected and appointed officials, employees, agents and representatives (individually and collectively hereinafter referred to as Indemnitees) from any liability, action, claim or damage whatsoever, based or asserted upon any services of CONTRACTOR, its officers, employees, subcontractors, agents or representatives arising out of or in any way relating to this Agreement, including but not limited to property damage, bodily injury, or death or any other element of any kind or nature. CONTRACTOR shall defend the Indemnitees at its sole expense including all costs and fees (including, but not limited, to attorney fees, cost of investigation, defense and settlements or awards) in any claim or action based upon such acts, omissions or services. COUNTY shall indemnify and hold harmless CONTRACTOR, its directors, officers, employees, agents and representatives (individually and collectively hereinafter referred to as

Countractor Indemnitees) from any liability whatsoever, based or asserted upon any act or omission of COUNTY, its officers, employees, subcontractors, agents or representatives arising out of or in any way relating to this Agreement, including but not limited to property damage, bodily injury or death or any other injury of any kind or nature whatsoever arising from the performance of COUNTY, its officers, employees, subcontractors, agents or representatives under this Agreement. COUNTY shall defend the Contractor Indemnitees in any claim or action based upon such alleged acts or omissions, at its sole expense, paying all costs and fees including, but not limited to, attorneys fees, cost of investigation, defense and settlements or awards.

- 21.2 With respect to any action or claim subject to indemnification herein by CONTRACTOR, CONTRACTOR shall, at their sole cost, have the right to use counsel of their own choice and shall have the right to adjust, settle, or compromise any such action or claim without the prior consent of COUNTY; provided, however, that any such adjustment, settlement or compromise in no manner whatsoever limits or circumscribes CONTRACTOR'S indemnification to Indemnitees as set forth herein. With respect to any action or claim subject to indemnification herein by COUNTY, COUNTY shall, at its sole cost, have the right to use counsel of its own choice and shall have the right to adjust, settle, or compromise any such action or claim without the prior consent of CONTRACTOR, provided, however, that any such adjustment, settlement or compromise in no manner whatsoever limits or circumscribes COUNTY'S indemnification to Contractor's Indemnitees as set forth herein.
- 21.3 CONTRACTOR'S obligation hereunder shall be satisfied when CONTRACTOR has provided to COUNTY the appropriate form of dismissal relieving COUNTY from any liability for the action or claim involved. COUNTY'S obligation hereunder shall be satisfied when COUNTY has provided to CONTRACTOR the appropriate form of dismissal relieving CONTRACTOR from any liability for the action or claim involved.
- 21.4 The specified insurance limits required in this Agreement shall in no way limit or circumscribe either party's obligations to indemnify and hold harmless the other or its Indemnitees herein from third party claims.
- 21.5 CONTRACTOR will not be liable to COUNTY or to any third party for any inability to procure and provide COUNTY with blood or blood products due to inadequate supplies of blood products from voluntary donations, strikes, work stoppages, acts of government, acts of God or other circumstances beyond the reasonable control of CONTRACTOR.

21.6 CONTRACTOR makes no representation or warranty, either express or implied, with respect to the products and services that are the subject of this Agreement, except for the representations and warranties expressly set forth in this Agreement.

22. Insurance

22.1 Without limiting or diminishing the CONTRACTOR'S obligation to indemnify or hold the COUNTY harmless, CONTRACTOR shall procure and maintain or cause to be maintained, at its sole cost and expense, the following insurance coverage's during the term of this Agreement. As respects to the insurance section only, the COUNTY herein refers to the County of Riverside, its Agencies, Districts, Special Districts, and Departments, their respective directors, officers, Board of Supervisors, employees, elected or appointed officials, agents, or representatives as Additional Insureds.

A. Workers' Compensation:

If the CONTRACTOR has employees as defined by the State of California, the CONTRACTOR shall maintain statutory Workers' Compensation Insurance (Coverage A) as prescribed by the laws of the State of California. Policy shall include Employers' Liability (Coverage B) including Occupational Disease with limits not less than \$1,000,000 per person per accident. The policy shall be endorsed to waive subrogation in favor of The County of Riverside.

B. Commercial General Liability:

Commercial General Liability insurance coverage, including but not limited to, premises liability, unmodified contractual liability, products and completed operations liability, personal and advertising injury, and cross liability coverage, covering claims which may arise from or out of CONTRACTOR'S performance of its obligations hereunder. Policy shall name the COUNTY as Additional Insured. Policy's limit of liability shall not be less than \$1,000,000 per occurrence combined single limit. If such insurance contains a general aggregate limit, it shall apply separately to this agreement or be no less than two (2) times the occurrence limit.

C. Vehicle Liability:

If vehicles or mobile equipment is used in the performance of the obligations under this Agreement, then CONTRACTOR shall maintain liability insurance for all owned, non-owned, or hired vehicles so used in an amount not less than \$1,000,000 per occurrence combined single limit. If such insurance contains a general aggregate limit, it shall apply separately to this agreement or be no less than two (2) times the occurrence limit. Policy shall name the COUNTY as Additional Insureds.

D. Professional Liability CONTRACTOR shall maintain Professional Liability insurance providing coverage for the CONTRACTOR'S performance of work included within this Agreement, with a limit of liability of not less than \$1,000,000 per occurrence and \$2,000,000 annual aggregate. If CONTRACTOR'S Professional Liability insurance is written on a claims made basis rather than an occurrence basis, such insurance shall continue through the term of this Agreement and CONTRACTOR shall purchase at his sole expense either 1) an Extended Reporting Endorsement (also known as Tail Coverage); or 2) Prior Dates Coverage from new insurer with a retroactive date back to the date of, or prior to, the inception of this Agreement; or 3) demonstrate through Certificates of Insurance that CONTRACTOR has maintained continuous coverage with the same or original insurer. Coverage provided under items 1), 2) or 3) will continue as long as the law allows.

E. General Insurance Provisions - All lines:

- 1) Any insurance carrier providing insurance coverage hereunder shall be admitted to the State of California and have an A M BEST rating of not less than A: VIII (A:8) unless such requirements are waived, in writing, by the County Risk Manager. If the County's Risk Manager waives a requirement for a particular insurer such waiver is only valid for that specific insurer and only for one policy term.
- 2) The CONTRACTOR and its sub-contractors must declare its insurance self-insured retention for each coverage required herein. If any such self-insured retention exceeds \$500,000 per occurrence each such retention shall have the prior written consent of the County Risk Manager before the commencement of operations under this Agreement. Upon notification of self-insured retention unacceptable to the COUNTY, and at the election of the Country's Risk Manager, CONTRACTOR'S carriers shall either; 1) reduce or eliminate such self-insured retention as respects this Agreement with the COUNTY, or 2) procure a bond which guarantees payment of losses and related investigations, claims administration, and defense costs and expenses.
- 3) CONTRACTOR shall cause CONTRACTOR'S insurance carrier(s) to furnish the County of Riverside with either 1) a properly executed original Certificate(s) of Insurance and certified original copies of Endorsements effecting coverage as required herein, and 2) if requested to do so orally or in writing by the County Risk Manager, provide original Certified copies of policies including all Endorsements and all attachments thereto, showing such insurance is in full force and effect. Further, said Certificate(s) and policies of insurance shall contain the covenant of the insurance carrier(s) that thirty (30) days written notice shall be given to the County of Riverside prior to any material modification, cancellation, expiration or

reduction in coverage of such insurance. In the event of a material modification, cancellation, expiration, or reduction in coverage, this Agreement shall terminate forthwith, unless the County of Riverside receives, prior to such effective date, another properly executed original Certificate of Insurance and original copies of endorsements or certified original policies, including all endorsements and attachments thereto evidencing coverage's set forth herein and the insurance required herein is in full force and effect. CONTRACTOR shall not commence operations until the COUNTY has been furnished original Certificate (s) of Insurance and certified original copies of endorsements and if requested, certified original policies of insurance including all endorsements and any and all other attachments as required in this Section. An individual authorized by the insurance carrier shall sign the original endorsements for each policy and the Certificate of Insurance.

- 4) It is understood and agreed to by the parties hereto that the CONTRACTOR'S insurance shall be construed as primary insurance, and the COUNTY'S insurance and/or deductibles and/or self-insured retention's or self-insured programs shall not be construed as contributory.
- 5) If, during the term of this Agreement or any extension thereof, there is a material change in the scope of services; or, there is a material change in the equipment to be used in the performance of the scope of work; or, the term of this Agreement, including any extensions thereof, exceeds five (5) years; the COUNTY reserves the right to adjust the types of insurance and the monetary limits of liability required under this Agreement, if in the County Risk Manager's reasonable judgment, the amount or type of insurance carried by the CONTRACTOR has become inadequate.
- 6) CONTRACTOR shall pass down the insurance obligations contained herein to all tiers of subcontractors working under this Agreement.
- 7) The insurance requirements contained in this Agreement may be met with a program(s) of self-insurance acceptable to the COUNTY.
- 8) CONTRACTOR agrees to notify COUNTY of any claim by a third party or any incident or event that may give rise to a claim arising from the performance of this Agreement.

23. General

- 23.1 CONTRACTOR shall not delegate or assign any interest in this Agreement, whether by operation of law or otherwise, without the prior written consent of COUNTY. Any attempt to delegate or assign any interest herein shall be deemed void and of no force or effect.
- 23.2 Any waiver by either party of any breach of any one or more of the terms of this Agreement shall not be construed to be a waiver of any subsequent or other breach of the same or of any other term of

this Agreement. Failure on the part of either party to require exact, full, and complete compliance with any terms of this Agreement shall not be construed as in any manner changing the terms or preventing either party from enforcement of the terms of this Agreement.

- 23.3 In the event the CONTRACTOR receives payment under this Agreement, which is later disallowed by COUNTY for nonconformance with the terms of the Agreement, the CONTRACTOR shall promptly refund the disallowed amount to the COUNTY on request; or at its option the COUNTY may offset the amount disallowed from any payment due to the CONTRACTOR.
- 23.4 CONTRACTOR shall not provide partial delivery or shipment of services or products unless specifically stated in the Agreement.
- 23.5 CONTRACTOR shall not provide any services or products subject to any chattel mortgage or under a conditional sales contract or other agreement by which an interest is retained by a third party. The CONTRACTOR warrants that it has good title to all materials or products used by CONTRACTOR or provided to COUNTY pursuant to this Agreement, free from all liens, claims, or encumbrances.
- 23.6 The COUNTY reserves the right to purchase more or less than the quantities specified in this Agreement.
- 23.7 The COUNTY agrees to cooperate with the CONTRACTOR in the CONTRACTOR's performance under this Agreement, including, if stated in the Agreement, providing the CONTRACTOR with reasonable facilities and timely access to COUNTY data, information, and personnel.
- 23.8 CONTRACTOR shall comply with all applicable Federal, State and local laws and regulations. CONTRACTOR will comply with all applicable COUNTY policies and procedures. In the event that there is a conflict between the various laws or regulations that may apply, the CONTRACTOR shall comply with the more restrictive law or regulation.
- 23.9 CONTRACTOR shall comply with all air pollution control, water pollution, safety and health ordinances, statutes, or regulations, which apply to performance under this Agreement.
- 23.10 CONTRACTOR shall comply with all requirements of the Occupational Safety and Health Administration (OSHA) standards and codes as set forth by the U.S. Department of Labor and the State of California (Cal/OSHA).

- 23.11 This Agreement shall be governed by the laws of the State of California. Any legal action related to the performance or interpretation of this Agreement shall be filed only in the Superior Court of the State of California located in Riverside, California, and the parties waive any provision of law providing for a change of venue to another location. In the event any provision in this Agreement is held by a court of competent jurisdiction to be invalid, void, or unenforceable, the remaining provisions will nevertheless continue in full force without being impaired or invalidated in any way.
- 23.12 This Agreement, including any attachments or exhibits, constitutes the entire Agreement of the parties with respect to its subject matter and supersedes all prior and contemporaneous representations, proposals, discussions and communications, whether oral or in writing. This Agreement may be changed or modified only by a written amendment signed by authorized representatives of both parties.

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Agreement.

COUNTY OF RIVERSIDE, a political subdivision of the State of California

Bv⊁ Kevin Jeffries, Chairman Board of Supervisors

Dated: APR **3 0 2019**

ATTEST:

Kecia Harper-Heem Clerk of the Board

APPROVED AS TO FORM:

Gregory P. Priamos County Counsel

> David McCarthy Knotine Realablez **Deputy County Counsel**

LifeStream

Frederick B. Axelród, M President/CEO/Medical Director

Attachment I

HIPAA Business Associate Agreement Addendum to Contract

Between the County of Riverside and Blood Bank of San Bernardino and Riverside Counties d/b/a LifeStream

This HIPAA Business Associate Agreement (the "Addendum") supplements, and is made part of the Underlying Agreement between the County of Riverside ("County") and Contractor and shall be effective as of the date the Underlying Agreement approved by both Parties (the "Effective Date").

RECITALS

WHEREAS, County and Contractor entered into the Underlying Agreement pursuant to which the Contractor provides services to County, and in conjunction with the provision of such services certain protected health information ("PHI") and/or certain electronic protected health information ("ePHI") may be created by or made available to Contractor for the purposes of carrying out its obligations under the Underlying Agreement; and,

WHEREAS, the provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Public Law 104-191 enacted August 21, 1996, and the Health Information Technology for Economic and Clinical Health Act ("HITECH") of the American Recovery and Reinvestment Act of 2009, Public Law 111-5 enacted February 17, 2009, and the laws and regulations promulgated subsequent thereto, as may be amended from time to time, are applicable to the protection of any use or disclosure of PHI and/or ePHI pursuant to the Underlying Agreement; and,

WHEREAS, County is a covered entity, as defined in the Privacy Rule; and,

WHEREAS, to the extent County discloses PHI and/or ePHI to Contractor or Contractor creates, receives, maintains, transmits, or has access to PHI and/or ePHI of County, Contractor is a business associate, as defined in the Privacy Rule; and,

WHEREAS, pursuant to 42 USC §17931 and §17934, certain provisions of the Security Rule and Privacy Rule apply to a business associate of a covered entity in the same manner that they apply to the covered entity, the additional security and privacy requirements of HITECH are applicable to business associates and must be incorporated into the business associate agreement, and a business associate is liable for civil and criminal penalties for failure to comply with these security and/or privacy provisions; and,

WHEREAS, the parties mutually agree that any use or disclosure of PHI and/or ePHI must be in compliance with the Privacy Rule, Security Rule, HIPAA, HITECH and any other applicable law; and,

WHEREAS, the parties intend to enter into this Addendum to address the requirements and obligations set forth in the Privacy Rule, Security Rule, HITECH and HIPAA as they apply to Contractor as a business associate of County, including the establishment of permitted and required uses and disclosures of PHI and/or ePHI created or received by Contractor during the course of performing functions, services and activities on behalf of County, and appropriate limitations and conditions on such uses and disclosures:

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, the parties agree as follows:

- 1. <u>Definitions</u>. Terms used, but not otherwise defined, in this Addendum shall have the same meaning as those terms in HITECH, HIPAA, Security Rule and/or Privacy Rule, as may be amended from time to time.
 - A. "Breach" when used in connection with PHI means the acquisition, access, use or disclosure of PHI in a manner not permitted under subpart E of the Privacy Rule which compromises the security or privacy of the PHI, and shall have the meaning given such term in 45 CFR §164.402.
 - (1) Except as provided below in Paragraph (2) of this definition, acquisition, access, use, or disclosure of PHI in a manner not permitted by subpart E of the Privacy Rule is presumed to be a breach unless Contractor

demonstrates that there is a low probability that the PHI has been compromised based on a risk assessment of at least the following four factors:

- (a) The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification;
- (b) The unauthorized person who used the PHI or to whom the disclosure was made;
- (c) Whether the PHI was actually acquired or viewed; and
- (d) The extent to which the risk to the PHI has been mitigated.

(2) Breach excludes:

- (a) Any unintentional acquisition, access or use of PHI by a workforce member or person acting under the authority of a covered entity or business associate, if such acquisition, access or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under subpart E of the Privacy Rule.
- (b) Any inadvertent disclosure by a person who is authorized to access PHI at a covered entity or business associate to another person authorized to access PHI at the same covered entity, business associate, or organized health care arrangement in which County participates, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted by subpart E of the Privacy Rule.
- (c) A disclosure of PHI where a covered entity or business associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.
- B. "Business associate" has the meaning given such term in 45 CFR §164.501, including but not limited to a subcontractor that creates, receives, maintains, transmits or accesses PHI on behalf of the business associate.
- C. "Data aggregation" has the meaning given such term in 45 CFR §164.501.
- D. "Designated record set" as defined in 45 CFR §164.501 means a group of records maintained by or for a covered entity that may include: the medical records and billing records about individuals maintained by or for a covered health care provider; the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or, used, in whole or in part, by or for the covered entity to make decisions about individuals.
- E. "Electronic protected health information" ("ePHI") as defined in 45 CFR §160.103 means protected health information transmitted by or maintained in electronic media.
- F. "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 such term in 42 USC §17921(5).
- G. "Health care operations" has the meaning given such term in 45 CFR §164.501.
- H. "Individual" as defined in 45 CFR §160.103 means the person who is the subject of protected health information.
- 1. "Person" as defined in 45 CFR §160.103 means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.
- J. "Privacy Rule" means the HIPAA regulations codified at 45 CFR Parts 160 and 164, Subparts A and E.
- K. "Protected health information" ("PHI") has the meaning given such term in 45 CFR §160.103, which includes ePHI.
- L. "Required by law" has the meaning given such term in 45 CFR §164.103.

- M. "Secretary" means the Secretary of the U.S. Department of Health and Human Services ("HHS").
- N. "Security incident" as defined in 45 CFR §164.304 means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.
- O. "Security Rule" means the HIPAA Regulations codified at 45 CFR Parts 160 and 164, Subparts A and C.
- P. "Subcontractor" as defined in 45 CFR §160.103 means a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.
- Q. "Unsecured protected health information" and "unsecured PHI" as defined in 45 CFR §164.402 means PHI not rendered unusable, unreadable, or indecipherable to unauthorized persons through use of a technology or methodology specified by the Secretary in the guidance issued under 42 USC §17932(h)(2).

2. Scope of Use and Disclosure by Contractor of County's PHI and/or ePHI.

- A. Except as otherwise provided in this Addendum, Contractor may use, disclose, or access PHI and/or ePHI as necessary to perform any and all obligations of Contractor under the Underlying Agreement or to perform functions, activities or services for, or on behalf of, County as specified in this Addendum, if such use or disclosure does not violate HIPAA, HITECH, the Privacy Rule and/or Security Rule.
- B. Unless otherwise limited herein, in addition to any other uses and/or disclosures permitted or authorized by this Addendum or required by law, in accordance with 45 CFR §164.504(e)(2), Contractor may:
 - 1) Use PHI and/or ePHI if necessary for Contractor's proper management and administration and to carry out its legal responsibilities; and,
 - 2) Disclose PHI and/or ePHI for the purpose of Contractor's proper management and administration or to carry out its legal responsibilities, only if:
 - a) The disclosure is required by law; or,
 - b) Contractor obtains reasonable assurances, in writing, from the person to whom Contractor will disclose such PHI and/or ePHI that the person will:
 - i. Hold such PHI and/or ePHI in confidence and use or further disclose it only for the purpose for which Contractor disclosed it to the person, or as required by law; and,
 - ii. Notify County of any instances of which it becomes aware in which the confidentiality of the information has been breached; and,
 - 3) Use PHI to provide data aggregation services relating to the health care operations of County pursuant to the Underlying Agreement or as requested by County; and,
 - 4) De-identify all PHI and/or ePHI of County received by Contractor under this Addendum provided that the de-identification conforms to the requirements of the Privacy Rule and/or Security Rule and does not preclude timely payment and/or claims processing and receipt.
- C. Notwithstanding the foregoing, in any instance where applicable state and/or federal laws and/or regulations are more stringent in their requirements than the provisions of HIPAA, including, but not limited to, prohibiting disclosure of mental health and/or substance abuse records, the applicable state and/or federal laws and/or regulations shall control the disclosure of records.

3. **Prohibited Uses and Disclosures.**

- A. Contractor may neither use, disclose, nor access PHI and/or ePHI in a manner not authorized by the Underlying Agreement or this Addendum without patient authorization or de-identification of the PHI and/or ePHI and as authorized in writing from County.
- B. Contractor may neither use, disclose, nor access PHI and/or ePHI it receives from County or from another business associate of County, except as permitted or required by this Addendum, or as required by law.
- C. Contractor agrees not to make any disclosure of PHI and/or ePHI that County would be prohibited from making.
- D. Contractor shall not use or disclose PHI for any purpose prohibited by the Privacy Rule, Security Rule, HIPAA and/or HITECH, including, but not limited to 42 USC §17935 and §17936. Contractor agrees:
 - 1) Not to use or disclose PHI for fundraising, unless pursuant to the Underlying Agreement and only if permitted by and in compliance with the requirements of 45 CFR §164.514(f) or 45 CFR §164.508;
 - 2) Not to use or disclose PHI for marketing, as defined in 45 CFR §164.501, unless pursuant to the Underlying Agreement and only if permitted by and in compliance with the requirements of 45 CFR §164.508(a)(3);
 - 3) Not to disclose PHI, except as otherwise required by law, to a health plan for purposes of carrying out payment or health care operations, if the individual has requested this restriction pursuant to 42 USC §17935(a) and 45 CFR §164.522, and has paid out of pocket in full for the health care item or service to which the PHI solely relates; and,
 - 4) Not to receive, directly or indirectly, remuneration in exchange for PHI, or engage in any act that would constitute a sale of PHI, as defined in 45 CFR §164.502(a)(5)(ii), unless permitted by the Underlying Agreement and in compliance with the requirements of a valid authorization under 45 CFR §164.508(a)(4). This prohibition shall not apply to payment by County to Contractor for services provided pursuant to the Underlying Agreement.

4. Obligations of County.

- A. County agrees to make its best efforts to notify Contractor promptly in writing of any restrictions on the use or disclosure of PHI and/or ePHI agreed to by County that may affect Contractor's ability to perform its obligations under the Underlying Agreement, or this Addendum.
- B. County agrees to make its best efforts to promptly notify Contractor in writing of any changes in, or revocation of, permission by any individual to use or disclose PHI and/or ePHI, if such changes or revocation may affect Contractor's ability to perform its obligations under the Underlying Agreement, or this Addendum.
- C. County agrees to make its best efforts to promptly notify Contractor in writing of any known limitation(s) in its notice of privacy practices to the extent that such limitation may affect Contractor's use or disclosure of PHI and/or ePHI.
- D. County agrees not to request Contractor to use or disclose PHI and/or ePHI in any manner that would not be permissible under HITECH, HIPAA, the Privacy Rule, and/or Security Rule.
- E. County agrees to obtain any authorizations necessary for the use or disclosure of PHI and/or ePHI, so that Contractor can perform its obligations under this Addendum and/or Underlying Agreement.

- 5. **Obligations of Contractor.** In connection with the use or disclosure of PHI and/or ePHI, Contractor agrees to:
 - A. Use or disclose PHI only if such use or disclosure complies with each applicable requirement of 45 CFR §164.504(e). Contractor shall also comply with the additional privacy requirements that are applicable to covered entities in HITECH, as may be amended from time to time.
 - B. Not use or further disclose PHI and/or ePHI other than as permitted or required by this Addendum or as required by law. Contractor shall promptly notify County if Contractor is required by law to disclose PHI and/or ePHI.
 - C. Use appropriate safeguards and comply, where applicable, with the Security Rule with respect to ePHI, to prevent use or disclosure of PHI and/or ePHI other than as provided for by this Addendum.
 - D. Mitigate, to the extent practicable, any harmful effect that is known to Contractor of a use or disclosure of PHI and/or ePHI by Contractor in violation of this Addendum.
 - E. Report to County any use or disclosure of PHI and/or ePHI not provided for by this Addendum or otherwise in violation of HITECH, HIPAA, the Privacy Rule, and/or Security Rule of which Contractor becomes aware, including breaches of unsecured PHI as required by 45 CFR §164.410.
 - F. In accordance with 45 CFR §164.502(e)(1)(ii), require that any subcontractors that create, receive, maintain, transmit or access PHI on behalf of the Contractor agree through contract to the same restrictions and conditions that apply to Contractor with respect to such PHI and/or ePHI, including the restrictions and conditions pursuant to this Addendum.
 - G. Make available to County or the Secretary, in the time and manner designated by County or Secretary, Contractor's internal practices, books and records relating to the use, disclosure and privacy protection of PHI received from County, or created or received by Contractor on behalf of County, for purposes of determining, investigating or auditing Contractor's and/or County's compliance with the Privacy Rule.
 - H. Request, use or disclose only the minimum amount of PHI necessary to accomplish the intended purpose of the request, use or disclosure in accordance with 42 USC §17935(b) and 45 CFR §164.502(b)(1).
 - I. Comply with requirements of satisfactory assurances under 45 CFR §164.512 relating to notice or qualified protective order in response to a third party's subpoena, discovery request, or other lawful process for the disclosure of PHI, which Contractor shall promptly notify County upon Contractor's receipt of such request from a third party.
 - J. Not require an individual to provide patient authorization for use or disclosure of PHI as a condition for treatment, payment, enrollment in any health plan (including the health plan administered by County), or eligibility of benefits, unless otherwise excepted under 45 CFR §164.508(b)(4) and authorized in writing by County.
 - K. Use appropriate administrative, technical and physical safeguards to prevent inappropriate use, disclosure, or access of PHI and/or ePHI.
 - L. Obtain and maintain knowledge of applicable laws and regulations related to HIPAA and HITECH, as may be amended from time to time.
 - M. Comply with the requirements of the Privacy Rule that apply to the County to the extent Contractor is to carry out County's obligations under the Privacy Rule.
 - N. Take reasonable steps to cure or end any pattern of activity or practice of its subcontractor of which Contractor becomes aware that constitute a material breach or violation of the subcontractor's obligations under the business associate contract with Contractor, and if such steps are unsuccessful, Contractor agrees to terminate its contract with the subcontractor if feasible.

- 6. Access to PHI, Amendment and Disclosure Accounting. Contractor agrees to:
 - A. Access to PHI, including ePHI. Provide access to PHI, including ePHI if maintained electronically, in a designated record set to County or an individual as directed by County, within five (5) days of request from County, to satisfy the requirements of 45 CFR §164.524.
 - B. Amendment of PHI. Make PHI available for amendment and incorporate amendments to PHI in a designated record set County directs or agrees to at the request of an individual, within fifteen (15) days of receiving a written request from County, in accordance with 45 CFR §164.526.
 - C. Accounting of disclosures of PHI and electronic health record. Assist County to fulfill its obligations to provide accounting of disclosures of PHI under 45 CFR §164.528 and, where applicable, electronic health records under 42 USC §17935(c) if Contractor uses or maintains electronic health records. Contractor shall:
 - 1) Document such disclosures of PHI and/or electronic health records, and information related to such disclosures, as would be required for County to respond to a request by an individual for an accounting of disclosures of PHI and/or electronic health record in accordance with 45 CFR §164.528.
 - 2) Within fifteen (15) days of receiving a written request from County, provide to County or any individual as directed by County information collected in accordance with this section to permit County to respond to a request by an individual for an accounting of disclosures of PHI and/or electronic health record.
 - Make available for County information required by this Section 6.C for six (6) years preceding the individual's request for accounting of disclosures of PHI, and for three (3) years preceding the individual's request for accounting of disclosures of electronic health record.
- 7. <u>Security of ePHI</u>. In the event County discloses ePHI to Contractor or Contractor needs to create, receive, maintain, transmit or have access to County ePHI, in accordance with 42 USC §17931 and 45 CFR §164.314(a)(2)(i), and §164.306, Contractor shall:
 - A. Comply with the applicable requirements of the Security Rule, and implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of ePHI that Contractor creates, receives, maintains, or transmits on behalf of County in accordance with 45 CFR §164.308, §164.310, and §164.312;
 - B. Comply with each of the requirements of 45 CFR §164.316 relating to the implementation of policies, procedures and documentation requirements with respect to ePHI;
 - C. Protect against any reasonably anticipated threats or hazards to the security or integrity of ePHI;
 - D. Protect against any reasonably anticipated uses or disclosures of ePHI that are not permitted or required under the Privacy Rule;
 - E. Ensure compliance with the Security Rule by Contractor's workforce;
 - F. In accordance with 45 CFR §164.308(b)(2), require that any subcontractors that create, receive, maintain, transmit, or access ePHI on behalf of Contractor agree through contract to the same restrictions and requirements contained in this Addendum and comply with the applicable requirements of the Security Rule;
 - G. Report to County any security incident of which Contractor becomes aware, including breaches of unsecured PHI as required by 45 CFR §164.410; and.
 - H. Comply with any additional security requirements that are applicable to covered entities in Title 42 (Public Health and Welfare) of the United States Code, as may be amended from time to time, including but not limited to HITECH.

- 8. **Breach of Unsecured PHI.** In the case of breach of unsecured PHI, Contractor shall comply with the applicable provisions of 42 USC §17932 and 45 CFR Part 164, Subpart D, including but not limited to 45 CFR §164.410.
 - A. **Discovery and notification.** Following the discovery of a breach of unsecured PHI, Contractor shall notify County in writing of such breach without unreasonable delay and in no case later than 60 calendar days after discovery of a breach, except as provided in 45 CFR §164.412.
 - 1) **Breaches treated as discovered.** A breach is treated as discovered by Contractor as of the first day on which such breach is known to Contractor or, by exercising reasonable diligence, would have been known to Contractor, which includes any person, other than the person committing the breach, who is an employee, officer, or other agent of Contractor (determined in accordance with the federal common law of agency).
 - 2) Content of notification. The written notification to County relating to breach of unsecured PHI shall include, to the extent possible, the following information if known (or can be reasonably obtained) by Contractor:
 - a) The identification of each individual whose unsecured PHI has been, or is reasonably believed by Contractor to have been accessed, acquired, used or disclosed during the breach;
 - b) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known;
 - c) A description of the types of unsecured PHI involved in the breach, such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved;
 - d) Any steps individuals should take to protect themselves from potential harm resulting from the breach;
 - A brief description of what Contractor is doing to investigate the breach, to mitigate harm to individuals, and to protect against any further breaches; and,
 - f) Contact procedures for individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, web site, or postal address.
 - B. **Cooperation.** With respect to any breach of unsecured PHI reported by Contractor, Contractor shall cooperate with County and shall provide County with any information requested by County to enable County to fulfill in a timely manner its own reporting and notification obligations, including but not limited to providing notice to individuals, prominent media outlets and the Secretary in accordance with 42 USC §17932 and 45 CFR §164.404, §164.406 and §164.408.
 - C. **Breach log.** To the extent breach of unsecured PHI involves less than 500 individuals, Contractor shall maintain a log or other documentation of such breaches and provide such log or other documentation on an annual basis to County not later than fifteen (15) days after the end of each calendar year for submission to the Secretary.
 - D. Delay of notification authorized by law enforcement. If Contractor delays notification of breach of unsecured PHI pursuant to a law enforcement official's statement that required notification, notice or posting would impede a criminal investigation or cause damage to national security, Contractor shall maintain documentation sufficient to demonstrate its compliance with the requirements of 45 CFR §164.412.
 - E. **Payment of costs.** With respect to any breach of unsecured PHI caused solely by the Contractor's failure to comply with one or more of its obligations under this Addendum and/or the provisions of HITECH, HIPAA, the Privacy Rule or the Security Rule, Contractor agrees to pay any and all costs associated with providing all legally required notifications to individuals, media outlets, and the Secretary. This provision shall not be

construed to limit or diminish Contractor's obligations to indemnify, defend and hold harmless County under Section 9 of this Addendum.

- F. **Documentation.** Pursuant to 45 CFR §164.414(b), in the event Contractor's use or disclosure of PHI and/or ePHI violates the Privacy Rule, Contractor shall maintain documentation sufficient to demonstrate that all notifications were made by Contractor as required by 45 CFR Part 164, Subpart D, or that such use or disclosure did not constitute a breach, including Contractor's completed risk assessment and investigation documentation.
- G. Additional State Reporting Requirements. The parties agree that this Section 8.G applies only if and/or when County, in its capacity as a licensed clinic, health facility, home health agency, or hospice, is required to report unlawful or unauthorized access, use, or disclosure of medical information under the more stringent requirements of California Health & Safety Code §1280.15. For purposes of this Section 8.G, "unauthorized" has the meaning given such term in California Health & Safety Code §1280.15(j)(2).
 - 1) Contractor agrees to assist County to fulfill its reporting obligations to affected patients and to the California Department of Public Health ("CDPH") in a timely manner under the California Health & Safety Code §1280.15.
 - 2) Contractor agrees to report to County any unlawful or unauthorized access, use, or disclosure of patient's medical information without unreasonable delay and no later than two (2) business days after Contractor detects such incident. Contractor further agrees such report shall be made in writing, and shall include substantially the same types of information listed above in Section 8.A.2 (Content of Notification) as applicable to the unlawful or unauthorized access, use, or disclosure as defined above in this section, understanding and acknowledging that the term "breach" as used in Section 8.A.2 does not apply to California Health & Safety Code §1280.15.

9. <u>Hold Harmless/Indemnification.</u>

- A. Contractor agrees to indemnify and hold harmless County, all Agencies, Districts, Special Districts and Departments of County, their respective directors, officers, Board of Supervisors, elected and appointed officials, employees, agents and representatives from any liability whatsoever, based or asserted upon any services of Contractor, its officers, employees, subcontractors, agents or representatives arising out of or in any way relating to this Addendum, including but not limited to property damage, bodily injury, death, or any other element of any kind or nature whatsoever arising from the performance of Contractor, its officers, agents, employees, subcontractors, agents or representatives from this Addendum. Contractor shall defend, at its sole expense, all costs and fees, including but not limited to attorney fees, cost of investigation, defense and settlements or awards, of County, all Agencies, Districts, Special Districts and Departments of County, their respective directors, officers, Board of Supervisors, elected and appointed officials, employees, agents or representatives in any claim or action based upon such alleged acts or omissions.
- B. With respect to any action or claim subject to indemnification herein by Contractor, Contractor shall, at their sole cost, have the right to use counsel of their choice, subject to the approval of County, which shall not be unreasonably withheld, and shall have the right to adjust, settle, or compromise any such action or claim without the prior consent of County; provided, however, that any such adjustment, settlement or compromise in no manner whatsoever limits or circumscribes Contractor's indemnification to County as set forth herein. Contractor's obligation to defend, indemnify and hold harmless County shall be subject to County having given Contractor written notice within a reasonable period of time of the claim or of the commencement of the related action, as the case may be, and information and reasonable assistance, at Contractor's expense, for the defense or settlement thereof. Contractor's obligation hereunder shall be satisfied when Contractor has provided to County the appropriate form of dismissal relieving County from any liability for the action or claim involved.
- C. The specified insurance limits required in the Underlying Agreement of this Addendum shall in no way limit or circumscribe Contractor's obligations to indemnify and hold harmless County herein from third party claims arising from issues of this Addendum.

- D. In the event there is conflict between this clause and California Civil Code §2782, this clause shall be interpreted to comply with Civil Code §2782. Such interpretation shall not relieve the Contractor from indemnifying County to the fullest extent allowed by law.
- E. In the event there is a conflict between this indemnification clause and an indemnification clause contained in the Underlying Agreement of this Addendum, this indemnification shall only apply to the subject issues included within this Addendum.
- 10. <u>Term.</u> This Addendum shall commence upon the Effective Date and shall terminate when all PHI and/or ePHI provided by County to Contractor, or created or received by Contractor on behalf of County, is destroyed or returned to County, or, if it is infeasible to return or destroy PHI and/ePHI, protections are extended to such information, in accordance with section 11.B of this Addendum.

11. **Termination.**

- A. **Termination for Breach of Contract.** A breach of any provision of this Addendum by either party shall constitute a material breach of the Underlying Agreement and will provide grounds for terminating this Addendum and the Underlying Agreement with or without an opportunity to cure the breach, notwithstanding any provision in the Underlying Agreement to the contrary. Either party, upon written notice to the other party describing the breach, may take any of the following actions:
 - 1) Terminate the Underlying Agreement and this Addendum, effective immediately, if the other party breaches a material provision of this Addendum.
 - 2) Provide the other party with an opportunity to cure the alleged material breach and in the event the other party fails to cure the breach to the satisfaction of the non-breaching party in a timely manner, the non-breaching party has the right to immediately terminate the Underlying Agreement and this Addendum.
 - 3) If termination of the Underlying Agreement is not feasible, the breaching party, upon the request of the non-breaching party, shall implement, at its own expense, a plan to cure the breach and report regularly on its compliance with such plan to the non-breaching party.

B. Effect of Termination.

- 1) Upon termination of this Addendum, for any reason, Contractor shall return or, if agreed to in writing by County, destroy all PHI and/or ePHI received from County, or created or received by the Contractor on behalf of County, and, in the event of destruction, Contractor shall certify such destruction, in writing, to County. This provision shall apply to all PHI and/or ePHI which are in the possession of subcontractors or agents of Contractor. Contractor shall retain no copies of PHI and/or ePHI, except as provided below in paragraph (2) of this section.
- 2) In the event that Contractor determines that returning or destroying the PHI and/or ePHI is not feasible, Contractor shall provide written notification to County of the conditions that make such return or destruction not feasible. Upon determination by Contractor that return or destruction of PHI and/or ePHI is not feasible, Contractor shall extend the protections of this Addendum to such PHI and/or ePHI and limit further uses and disclosures of such PHI and/or ePHI to those purposes which make the return or destruction not feasible, for so long as Contractor maintains such PHI and/or ePHI.

12. **General Provisions.**

- A. **Retention Period.** Whenever Contractor is required to document or maintain documentation pursuant to the terms of this Addendum, Contractor shall retain such documentation for 6 years from the date of its creation or as otherwise prescribed by law, whichever is later.
- B. **Amendment.** The parties agree to take such action as is necessary to amend this Addendum from time to time as is necessary for County to comply with HITECH, the Privacy Rule, Security Rule, and HIPAA generally.
- C. Survival. The obligations of Contractor under Sections 3, 5, 6, 7, 8, 9, 11.B and 12.A of this Addendum shall survive the termination or expiration of this Addendum.

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- D. Regulatory and Statutory References. A reference in this Addendum to a section in HITECH, HIPAA, the Privacy Rule and/or Security Rule means the section(s) as in effect or as amended.
- E. **Conflicts.** The provisions of this Addendum shall prevail over any provisions in the Underlying Agreement that conflict or appear inconsistent with any provision in this Addendum.

F. Interpretation of Addendum.

- 1) This Addendum shall be construed to be part of the Underlying Agreement as one document. The purpose is to supplement the Underlying Agreement to include the requirements of the Privacy Rule, Security Rule, HIPAA and HITECH.
- 2) Any ambiguity between this Addendum and the Underlying Agreement shall be resolved to permit County to comply with the Privacy Rule, Security Rule, HIPAA and HITECH generally.
- G. Notices to County. All notifications required to be given by Contractor to County pursuant to the terms of this Addendum shall be made in writing and delivered to the County both by fax and to both of the addresses listed below by either registered or certified mail return receipt requested or guaranteed overnight mail with tracing capability, or at such other address as County may hereafter designate. All notices to County provided by Contractor pursuant to this Section shall be deemed given or made when received by County.

County HIPAA Privacy Officer:

HIPAA Privacy Manager

County HIPAA Privacy Officer Address:

26520 Cactus Avenue,

Moreno Valley, CA 92555

County HIPAA Privacy Officer Phone Number: (951) 486-6471

EXHIBIT A1 SCOPE OF SERVICE

Blood and Laboratory Services

CONTRACTOR RESPONSIBILITIES

- 1. CONTRACTOR agrees to provide blood components that are collected, tested, processed, labeled, handled, stored and transported according to the standards of the Food and Drug Administration ("FDA"), the AABB, and the State of California.
- 2. CONTRACTOR shall test blood for conditions required by the FDA, state and local laws and other applicable standards. Such tests shall include, but not be limited to:

ABO/Rh

Irregular red cell antibodies

Syphilis

Hepatitis B and C

HIV

HTLV-1/11

West Nile virus

Chagas disease

- 3. Testing does not guarantee that a given blood component is incapable of transmitting an infectious disease such as hepatitis, AIDS or other blood borne illness.
- 4. CONTRACTOR shall notify COUNTY to return any blood components when a unit in its inventory is from a donor who subsequently tests positive/repeatedly reactive for an infectious marker, or when post donation information is obtained which would have made the donor ineligible at time of donation.
- 5. Following FDA requirements, CONTRACTOR shall notify COUNTY in writing when blood components it provided to COUNTY came from a donor who subsequently is determined to be infected with or at increased risk of transmitting HIV and/or HCV, or when post donation information is obtained which would have made the donor ineligible at time of donation. NOTE: CONTRACTOR initial notification process utilizes email as primary communication vehicle.

Reference 21CFR610.46-48, 21CFR630.6, and AABB Standards 5.4.1.2

- a. CONTRACTOR will notify COUNTY within three (3) calendar days after CONTRACTOR has determined that the COUNTY was supplied with blood and/or blood components collected from a donor who tested negative at the time of donation and subsequently tests reactive for HIV or HCV infection on a later donation, or subsequently is determined to be at increased risk for transmitting HIV or HCV infection.
- b. CONTRACTOR will notify COUNTY of the results of any supplemental test for HIV or HCV, or other relevant follow-up testing required by the FDA within 30 days of the HIV or HCV screening test.
- 6. CONTRACTOR will provide clinical consultations concerning transfusion problems, test methods, specifications and performance, including assistance in dealing with cross-matching problems and needs for special blood, if requested by COUNTY.

- 7. CONTRACTOR will provide COUNTY with as many copies of the most current version of <u>The Circular of Information for the Use of Human Blood and Blood Components</u> as requested, at no cost to COUNTY.
- 8. CONTRACTOR shall sponsor regular continuing education events pertinent to blood banking.
- 9. Services under this Agreement will be provided upon CONTRACTOR's receipt of either an oral or written order from a person authorized by COUNTY to make such orders.
- 10. CONTRACTOR shall ship blood and blood components to the COUNTY in the amounts requested by the COUNTY, in accordance with CONTRACTOR's inventory. COUNTY understands that delivery schedules will be based on the urgency of need and the proximity of the COUNTY to the CONTRACTOR's location. CONTRACTOR may offer to substitute alternative items if items requested by COUNTY are not available when needed. Each shipment will be properly packaged and will be accompanied by an itemized shipping list or other documentation.
- 11. CONTRACTOR will give full credit for in-dated red cells, frozen plasma, apheresis platelets, and cryoprecipitate originally provided by CONTRACTOR, when properly stored and shipped, for any one of the following reasons:
 - return is requested by the CONTRACTOR
 - the component cannot be used for some technical reason (except for those technical reasons controlled by the COUNTY)
 - the COUNTY has notified the CONTRACTOR and has allowed the CONTRACTOR the opportunity to transfer the units to another facility. Minimum notice for red cells is 7 days before outdate; for platelets it is 24 hours before outdate; and for frozen products it is 90 days before outdate
- 12. CONTRACTOR will not allow return credit for the following components:

pediatric units

autologous & directed units

washed red cells

granulocyte apheresis

frozen red cells, thawed

frozen red cells

altered or modified components

components with altered or defaced labels

red cells with less than 2 segments integrally attached

liquid plasma

reconstituted whole blood

whole blood

and

CONTRACTOR will not allow return credit of the additional fee charged for the following ordered services:

irradiation

pooling

CMV screening

volume reduction

antigen screening

Hemoglobin S screening

- 13. CONTRACTOR will notify COUNTY immediately of any discrepancies between components shipped or returned, or services provided and corresponding paperwork.
- 14. In conformance with the Omnibus Reconciliation Act of 1980 (Public Law 96-499), the Secretary, United States Department of Health and Human Services, or the Secretary's designee, will be permitted access to any books and records of COUNTY or CONTRACTOR during the term of this Agreement and for a four (4) year period after termination of this Agreement.
- 15. CONTRACTOR agrees that all information, records and data collected or maintained about patients shall be confidential. CONTRACTOR, its employees and agents shall maintain the confidentiality of all patient information received in the course of providing Services under this Agreement. No employee or agent of CONTRACTOR shall discuss, transmit or narrate in any manner any patient information of a personal, medical or other nature except as a necessary part of providing Services to the patient.
- 16. CONTRACTOR shall evaluate reported cases of possible transfusion complications (reactions and infections), investigate the involved donors and donations appropriately and return an investigation summary and case assessment to the reporting hospital. If appropriate, the COUNTY will provide specimens of the recipient's blood and portions of the remaining blood component to the CONTRACTOR for evaluation as part of the case investigation.
- 17. CONTRACTOR agrees to provide regularly scheduled delivery service for shipments, at no charge to COUNTY. CONTRACTOR agrees to provide COUNTY with transportation for supplemental and emergency orders for a fee (as defined in Attachment A).
- 18. CONTRACTOR shall provide a blood utilization management program to COUNTY for the term of this agreement at no additional charge, to include the following:
 - a. Collaborate with COUNTY medical staff to establish evidence based best practice transfusion criteria and laboratory practices, to include retrospective audit criteria, and prospective gatekeeping criteria
 - b. Recommend prospective transfusion gatekeeping trigger criteria and provide secondary support of prospective gatekeeping by COUNTY pathologists
 - c. Provide secondary retrospective case review of outlier transfusion practices
 - d. Participate in COUNTY transfusion committee meetings
 - e. Recommend and support follow up communication to COUNTY physicians prescribing outside of best practice transfusion criteria

COUNTY RESPONSIBILITIES

- 1.COUNTY shall maintain an accredited laboratory with licensed medical technologists as required by California state law.
- 2. COUNTY will designate personnel who are authorized to order blood components and testing services, and receive test results.

- 3. COUNTY shall maintain temperature-monitored facilities that meet the standards of the FDA and AABB for the storage of blood components received from CONTRACTOR. A CONTRACTOR representative may periodically inspect these storage facilities.
- 4. COUNTY shall comply with directives of CONTRACTOR concerning handling, storage and shipping of blood components, blood samples, and related documentation.
- 5. When utilizing reference laboratory services, COUNTY will provide patient samples that conform to collection criteria and conditions defined by CONTRACTOR.
- 6. COUNTY acknowledges that during periods of limited inventories, CONTRACTOR will fill orders based on urgency of individual patient requirements.
- 7. In order to minimize delivery expenses for supplemental and emergency blood orders and assist CONTRACTOR in managing the community blood supply, COUNTY shall establish appropriate inventory levels representing a normal type distribution; agree with CONTRACTOR to a regular schedule of stock deliveries and routinely use blood components with the shortest remaining dating period when appropriate. COUNTY shall designate an employee who shall work with CONTRACTOR employees on the foregoing matters.
- 8. COUNTY shall place regular stock orders using form or other means approved by CONTRACTOR.
- 9. COUNTY shall make available to CONTRACTOR, as necessary, its inventory of blood components in excess of COUNTY's immediate needs. Refusal to return a blood component to CONTRACTOR for transfer to another hospital with an urgent need negates COUNTY's return for credit privilege for that component. (See CONTRACTOR Responsibilities Section, Item 11)
- 10. COUNTY shall make requests on a factual need basis using "Code 1" (STAT) only for true emergency usage. STAT requests for more than four (4) units of Group O or Rh-negative shall require the approval of a CONTRACTOR Medical Director.
- 11. COUNTY will accept the responsibility for delivery charges when the COUNTY specifically requests the emergency delivery of blood by ambulance or helicopter even though CONTRACTOR vehicles, bus, courier or cab are available.
- 12. COUNTY shall maintain complete records of the recipients of each of CONTRACTOR's blood components sufficient to allow tracing to the patient in the event of a product withdrawal or recall, and to allow investigation of potential transfusion complications.
- 13. COUNTY shall furnish the CONTRACTOR with the identification of transfused components and sufficient clinical information to permit independent case assessment whenever a transfusion recipient develops a complication (reaction or infection) that was or may have been transfusion mediated and any aspect of manufacture (including donor selection) may have contributed. If such a transfusion complication involves a fatality, the COUNTY will notify the CONTRACTOR immediately. This reporting and evaluation is required by the FDA (Code of Federal Regulations, Title 21, 606.170). Special forms will be provided by the CONTRACTOR for this purpose.

- 14. COUNTY will notify the CONTRACTOR of problems with components (e.g., hemolysis, labeling irregularities, typing discrepancies, possible bacterial contamination) without delay upon discovery.
- 15. To facilitate and expedite the withdrawal/recall process and CONTRACTOR notification to COUNTY, COUNTY will provide CONTRACTOR with valid email contacts, and maintain currency of contact information.
- 16. COUNTY will immediately return blood or blood components requested by CONTRACTOR as part of market withdrawal procedures, and if component is no longer in inventory, inform the CONTRACTOR. To ensure the integrity of market withdrawal and recall processes, COUNTY will not extend the shelf-life of any blood component by performing additional manufacturing e.g., freezing red blood cells.
- 17. Following FDA Lookback requirements, COUNTY will notify recipients of blood components from donors subsequently determined to be infected with HIV and/or HCV and provide written confirmation of the receipt of the CONTRACTOR's notification with component disposition information.
- 18. COUNTY will notify the CONTRACTOR immediately in writing of any change in ownership of COUNTY or change in the director of the Transfusion Service.
- 19. COUNTY will actively and exclusively support the blood and marrow donor recruitment efforts of the CONTRACTOR by sponsoring, hosting and encouraging employee participation in regularly scheduled and/or special blood and/or marrow drives.
- 20. COUNTY shall serologically confirm ABO of red blood cell and granulocyte components prior to transfusing unit.
- 21. COUNTY agrees that all information and data collected or maintained about donors and donations shall be confidential. COUNTY, its employees and agents shall maintain the confidentiality of all information received in the course of using blood components provided under this Agreement. No employee or agent of the COUNTY shall discuss, transmit or narrate in any manner any donor or donation information except as a necessary part of providing services to patients and performing assigned work duties.
- 22. COUNTY shall cooperate and participate with CONTRACTOR to effect a successful blood utilization management program, to include the following:
 - a. Provide, at its sole expense, non-admitting privileges for CONTRACTOR medical staff, to facilitate interactions with COUNTY medical and hospital staff and access to patient and case information
 - b. Collaborate with CONTRACTOR to establish or modify evidence based best practice transfusion criteria and laboratory practices
 - c. Collaborate with CONTRACTOR to develop gatekeeping trigger criteria levels and provide prospective review of transfusion requests outside of the established levels
 - d. Provide QA or other COUNTY designated clinical review staff to conduct quarterly primary case audits of transfusion practices using established criteria to identify outlier cases
 - e. Establish and/or maintain regularly scheduled transfusion committee meetings with invitations extended CONTRACTOR medical staff

- f. Establish follow up peer communication to COUNTY physicians prescribing outside of best practices criteria
- g. Provide utilization reporting by top blood utilizing MDC or DRG group to facilitate establishing baseline data and monitoring success towards blood utilization improvement goals.

EXHIBIT A2 Scope of Services --

Therapeutic Apheresis Services ("TA")

CONTRACTOR Responsibilities.

- 1. CONTRACTOR shall provide Nurses who have met the necessary standards to conduct TA procedures, and shall have completed special preparation or certification for the performance of TA. All Nurses shall possess a current valid license issued by the California Board of Registered Nursing. Each Nurse shall carry a copy of his or her license and shall, upon request from COUNTY, present said license prior to rendering services at the COUNTY. CONTRACTOR shall maintain on file appropriate evidence that such standards are met, and shall make such evidence available to COUNTY upon request.
- 2. CONTRACTOR shall provide FDA-cleared apheresis equipment and all disposables and anticoagulant solutions required for the procedure. The equipment shall be maintained and transported to and from COUNTY by CONTRACTOR.
- 3. CONTRACTOR medical staff shall provide medical consultation to COUNTY staff upon request.
- 4. CONTRACTOR shall provide procedure specific and quality assurance documents and reports required by COUNTY in order to comply with COUNTY policies, federal, state, and local regulations, Joint Commission, and other agencies as determined by COUNTY.
- 5. CONTRACTOR personnel, including Nurses, shall dispose of medical waste as required by COUNTY.
- 6. CONTRACTOR Nurses shall complete patient medical records in accordance with COUNTY policy.
- 7. CONTRACTOR and its independent contractors shall at all times identify themselves as "CONTRACTOR" and title, to include the continuous display of a photo ID badge. Photo ID badges will be provided by and paid for by CONTRACTOR. At no time shall CONTRACTOR or any of its independent contractors identify themselves as employees or agents of COUNTY, either verbally, by implication or by wearing an item which names or identifies COUNTY.
- 8. CONTRACTOR will train a COUNTY staff nurse on emergency shutdown of equipment.
- 9. The TA procedure will be conducted in accordance with general guidelines approved by COUNTY's medical staff and utilization review/quality assurance department.
- 10. CONTRACTOR shall offer its services Monday through Friday, 7 a.m. to 5 p.m. Emergency services shall be available 24 hours a day, 7 days a week in emergency situations as determined by COUNTY with minimum of 4 hours advance notice.
- 11. CONTRACTOR shall provide emergency service in the event the patient's clinical condition dictates such response, as determined by the patient's supervising physician.
- 12. CONTRACTOR shall conduct periodic meetings with COUNTY TA services referral staff to facilitate communication and ensure consistent quality and customer service.

COUNTY Responsibilities.

- 1. COUNTY shall provide CONTRACTOR staff with basic orientation to COUNTY policies and procedures, including, but not limited to: dress code; identification badge requirements; reporting of industrial injuries and illnesses; emergencies fire, natural disasters, cardiac/respiratory; computerized systems; hazardous waste disposal.
- 2. COUNTY shall provide CONTRACTOR staff with protective wear, as required to ensure compliance with OSHA regulations.
- 3. COUNTY shall provide miscellaneous supplies and equipment, including but not limited to: electrodes and monitoring equipment, non-invasive blood pressure monitoring equipment, iv

- infusion pumps and tubing, iv administration sets, priming and replacement fluids, gloves, surgical masks blood administration sets and appropriate blood filters, pressure wrap bandages, and any medications prescribed by patient's supervising physician as may be needed to support the provision of TA services.
- 4. COUNTY shall provide appropriate replacement fluids for the TA procedure as recommended by the CONTRACTOR's medical staff.
- 5. COUNTY shall provide appropriate space with necessary utilities and communications equipment for conducting TA procedures, and allow CONTRACTOR staff access to parking, restrooms, cafeteria, and other public facilities available to COUNTY staff.
- 6. COUNTY shall provide all general nursing care, including emergency care and medications to TA patients, before, during and after the TA procedure, and shall be responsible for transporting patients to and from the treatment location if required. COUNTY agrees that except as related to the provision of TA services, CONTRACTOR clinical staff shall not in any way undertake the practice of nursing nor practice of medicine.
- 7. COUNTY shall cooperate in scheduling procedures, including notifying CONTRACTOR 24 hours in advance of required treatment, with a minimum of 4 hours' notice for emergent procedures. Non-emergent procedures shall be scheduled as mutually agreed by CONTRACTOR and COUNTY.
- 8. At all times during the term of this Agreement, COUNTY shall be licensed as an acute care hospital in the state of California, shall be a participating provider in the Medicare program, and shall be solely responsible for its compliance with all licensure, regulatory, accreditation, and reimbursement requirements.
- 9. COUNTY shall have full medical and administrative responsibility for its patients in general, and specifically, during the provision of TA services. Accordingly, COUNTY agrees to ensure the availability of a qualified, duly licensed and registered, credentialed physician with appropriate COUNTY staff privileges, to supervise care of its patients during the provision of TA services.
- 10. COUNTY or its licensed physician retains responsibility for patient care before, during and after the procedure and for providing written orders for the TA procedure. COUNTY or its licensed physician shall have no right to control the detail, manner or methods by which CONTRACTOR clinical staff perform the TA services
- 11. COUNTY or its licensed physician will inform the patient of the need for and anticipated risks and benefits of the prescribed procedure. In addition, CONTRACTOR and/or CONTRACTOR's clinical staff shall obtain a signed informed consent for the procedure from the patient, or his/her legal representative and shall provide COUNTY and patient with a copy of the signed form.
- 12. COUNTY shall provide CONTRACTOR and/or CONTRACTOR's clinical staff access to the patient's medical record, including patient's supervising physician's written order for TA services, documentation of medical necessity, and other patient information in accordance with COUNTY and its medical staff policies and procedures.
- 13. COUNTY shall provide resuscitation back-up on premises with staff available to provide emergency support, if needed, including a staff nurse to be trained by CONTRACTOR on emergency shutdown of equipment.
- 14. COUNTY shall provide placement and maintenance of a dual-lumen apheresis venous catheter, when required. CONTRACTOR shall notify hospital of placement requirements as applicable.
- 15. All federal, state, and local licenses or permits which are required for the services provided herein are the responsibility of COUNTY.
- 16. In the event that a special device is prescribed (e.g. immunoadsorption column) in conjunction with the TA procedure, it shall be supplied by COUNTY. CONTRACTOR may provide the device, upon COUNTY's request, subject to availability.

- 17. In the event that a scheduled procedure is canceled, it is the responsibility of COUNTY to inform CONTRACTOR of the cancellation prior to a Nurse being sent. Otherwise, COUNTY will be invoiced for the Nurse's time in accordance with the fee schedule set forth in Attachment "1".
- 18. COUNTY shall make its TA referral staff available for periodic meetings with CONTRACTOR to facilitate communication and ensure consistent quality and customer service.

EXHIBIT B PAYMENT PROVISIONS

RIVERSIDE UNIVERSITY HEALTH SYSTEM	FEE-2019	FEE-2020	FEE-2021	FEE-2022	FEE-2023
RED BLOOD CELL COMPONENTS					
Red blood cells, packed (RBCs)	225.25	229.25	234.25	238.25	243.25
Red blood cells, leukocytes reduced by filtration	225.25	229.25	234.25	238.25	243.25
Red blood cells, frozen, deglycerolized	447.25	451.25	456.25	460.25	465.25
Red blood cells, pediatric aliquots, leukocytes reduced by filtration	395.00	395.00	395.00	395.00	395.00
(with CMV screening) approximately 25 ml each x 8					
Whole Blood	330.00	330.00	330.00	330.00	330.00
Reconstituted Whole Blood	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00
PLASMA COMPONENTS					
Apheresis Fresh Frozen Plasma 400-499 mls	100.00	100.00	100.00	100.00	100.00
Apheresis Fresh Frozen Plasma (Part A-C), 200-399 mls each	39.00	40.00	41.00	42.00	43.00
Apheresis Fresh Frozen Plasma, pediatric aliquots, approx. 45 ml each x 8	400.00	400.00	400.00	400.00	400.00
Plasma, fresh frozen, cryoprecipitate reduced	39.00	40.00	41.00	42.00	43.00
Plasma, frozen within 24 hours, 200-300 mls	39.00	40.00	41.00	42.00	43.00
Liquid Plasma	80.00	80.00	80.00	80.00	80.00
CRYOPRECIPITATE COMPONENTS					
Cryoprecipitated AHF, per unit	39.00	40.00	41.00	42.00	43.00
Cryoprecipitated AHF, pooled, (5 units) - Includes Pooling	335.00	340.00	345.00	350.00	350.00
PLATELET COMPONENTS					
Platelets, apheresis, leukocytes reduced	446.25	451.25	456.25	461.25	466.25
Platelets, apheresis, leukocytes reduced, divided (with CMV screening and irratiation), 100-400 mls each	745.00	745.00	745.00	745.00	745.00
Granulocytes, apheresis	3,000.00	3,500.00	3,500.00	3,500.00	3,500.00

Platelets, apheresis, leukocytes reduced,	250.00	250.00	250.00	250.00	250.00
divided (with CMV screening and					
irratiation), 100-400 mls each					
SPECIAL COMPONENT PROCEDURES (2)					
Volume reduction	100.00	100.00	100.00	100.00	100.00
Pooling	_	_	_	-	
Irradiation	40.00	40.00	40.00	40.00	40.00
Washing of components	150.00	150.00	150.00	150.00	150.00
Freezing or thawing of red cells, (includes deglycerolization)	222.00	222.00	222.00	222.00	222.00
PRIORITY AND DELIVERY					
CHARGES					
"Code One"/STAT delivery or pick up	75.00	75.00	75.00	75.00	75.00
Scheduled delivery or pick up	NO CHARGE	NO CHARGE	NO CHARGE	NO CHARGE	NO CHARGE
AUTOLOGOUS AND DIRECTED SERVICES (2)					
Laboratory testing includes Phlebotomy:					
ABO/Rh	64.00	64.00	64.00	64.00	64.00
Anti-CMV	62.00	62.00	62.00	62.00	62.00
Predonation test panel	75.00	75.00	75.00	75.00	75.00
Autologous handling fee	100.00	100.00	100.00	100.00	100.00
Directed handling fee (Includes irradiation)	140.00	140.00	140.00	140.00	140.00
(2) Charged in addition to component fee(s)					
OTHER SERVICES AND SUPPLIES					
Shipping (up to 6 units)	100.00	100.00	100.00	100.00	100.00
	or cost				
Therapeutic phlebotomy at LifeStream	100.00	100.00	100.00	100.00	100.00
Therapeutic phlebotomy inpatient (see					
Therapeutic Apheresis Fee Schedule)	20.50	20.50	20.50	20.50	20.50
Blood bags - dual, with inline leuko filter attached (each set)	28.50	28.50	28.50	28.50	28.50
Blood bags - triple, with inline leuko filter attached (each set)	29.50	29.50	29.50	29.50	29.50
600 ML, transfer packs (each)	4.50	4.50	4.50	4.50	4.50
Attach satellite bag (sterile docking)	25.00	25.00	25.00	25.00	25.00

CLINICAL / DECEDENCE					
CLINICAL / REFERENCE LABORATORY TESTING					
LABORATORT TESTING					
ABO discrepancy resolution	150.00	150.00	150.00	150.00	150.00
ABO typing	20.00	20.00	20.00	20.00	20.00
Acidified Serum Test PNH	200.00	200.00	200.00	200.00	200.00
Antibody ID panel (LISS)	90.00	90.00	90.00	90.00	90.00
Antibody ID panel (PEG)	90.00	90.00	90.00	90.00	90.00
Antibody Screen	100.00	100.00	100.00	100.00	100.00
Antibody Titer	150.00	150.00	150.00	150.00	150.00
Anti-CMV	40.00	40.00	40.00	40.00	40.00
Chemical or drug treatment of reagent	100.00	100.00	100.00	100.00	100.00
cells					
Crossmatch	118.00	118.00	118.00	118.00	118.00
DAT - Anti - Complement	20.00	20.00	20.00	20.00	20.00
DAT - Anti - IgG	20.00	20.00	20.00	20.00	20.00
DAT Polyspecific	20.00	20.00	20.00	20.00	20.00
Differential adsorption of serum, per	95.00	95.00	95.00	95.00	95.00
adsorption					
Dilution	30.00	30.00	30.00	30.00	30.00
Elution	70.00	70.00	70.00	70.00	70.00
Enzyme treatment of panel	100.00	100.00	100.00	100.00	100.00
Fetal maternal hemorrhage	150.00	150.00	150.00	150.00	150.00
Hemoglobin S Screening (Sickle Cell)	39.00	39.00	39.00	39.00	39.00
HLA matching of components	312.00	312.00	312.00	312.00	312.00
Incubation of serum with drugs or	300.00	300.00	300.00	300.00	300.00
chemicals					- 0- 10
Inhibition of serum	100.00	100.00	100.00	100.00	100.00
Patient Serum Screen	55.00	55.00	55.00	55.00	55.00
Phenotype (for each antigen)	40.00	40.00	40.00	40.00	40.00
Phenotype, molecular, red blood cell (per	500.00	500.00	500.00	500.00	500.00
patient)					
Phlebotomy	22.00	22.00	22.00	22.00	22.00
Platelet antibody screen	300.00	300.00	300.00	300.00	300.00
Platelets, apheresis crossmatch (does not	400.00	400.00	400.00	400.00	400.00
include component)					
Reticulocyte Separation	75.00	75.00	75.00	75.00	75.00
Rh phenotype (C,c,E,e)	75.00	75.00	75.00	75.00	75.00
Rh (D) typing	22.00	22.00	22.00	22.00	22.00
STAT laboratory procedure	95.00	95.00	95.00	95.00	95.00
Super Coombs	36.00	36.00	36.00	36.00	36.00
Titration	150.00	150.00	150.00	150.00	150.00
Transfusion Review	225.00	225.00	225.00	225.00	225.00

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Type and Screen	138.00	138.00	138.00	138.00	138.00
Unit Search Charge	110.00	110.00	110.00	110.00	110.00
Antigen Typing, Class I: C, E, N, K and	65.00	65.00	65.00	65.00	65.00
S (screen for ag neg blood per ag per unit)					<u> </u>
Antigen Typing, Class II: e, s, c, Fya, Jka,	115.00	115.00	115.00	115.00	115.00
Jkb, M and Cw (screen for ag neg blood					
per ag per unit)	170.00	1 = 0 0 0	15000	15000	
Antigen Typing, Rare: all others (screen	170.00	170.00	170.00	170.00	170.00
for ag neg blood per ag per unit)					
PLASMAPHERESIS (Therapeutic Plasm	a Exchange)				
Routine (first four 4hours of service, weekdays 0700-1700)			1,389.00	PLROUT	
·	,				
After Hours (1700-0700 or weekend/Holiday)	•		1,826.00	PLWKHL	
•					
Cancelation Fee			141.00	PLCANC	
Abort Procedure			692.00	PLABOR	
Extended Hours (after initial 4 hours of service)			315.00	PLEXT	
Delay initiation of treatment due to facility issue (per hour)			135.00	DELAY	
•					
CYTAPHERESIS (Includes White Blood Exchange or Reduction)	Cell Depletion	on, Platelet l	Depletion, and	d Red Blood	Cell
	0700 1700)		1.577.00	CVD	NI I'D
Routine (first four 4hours of service, weekdays	0700-1700)		1,577.00	CYROUT	
A.O. II. (4700.0700			1.026.00		
After Hours (1700-0700 or weekend/Holiday)			1,826.00	CYWI	KHL
Cancelation Fee		141.00	CVCA	NC	
Cancelation ree			141.00	CYCANC	
Abort Procedure			692.00	CYAI	POP
Abort Procedure			092.00	CIAI	DOK
Extended Hours (after initial 4 hours of service)			315.00	CYEXT	
Delay initiation of treatment due to facility issue (per hour)			135.00	DEL	AY
Delay initiation of treatment due to facility is	obae (per noar		ļ		
Delay initiation of treatment due to facility is THERAPEUTIC PHLEBOTOMY	——————————————————————————————————————				
	- The second of		292.00	ITHF	PHR

After Hours (1700-0700) or Weekend/Holidays	580.00	WTHPHB
Cancellation Fee	141.00	PLCANC
EQUIPMENT TRANSPORT WITHOUT PROCEDUE	370.00	EQUIP
EDUCATION /TRAINING OF APHERESIS STAFF (per hour and includes staff hospital orientation, HOSPITAL-specific protocols)	125.00	EDUC

Fees are subject to all applicable taxes. Treatments include set-up of the Apheresis System, priming of the extracorporeal blood circuit, withdrawal, processing and return of the patient's blood components as prescribed, and monitoring of the patient's treatment throughout the procedure.

The Apheresis System will not be permanently placed at the hospital but shall be made available on an "as required" basis to support clinical procedures.

Apheresis treatment fees include the cost of transferring the Apheresis System to the hospital and set-up; apheresis fees do not include normal saline and/or blood products used for priming the Apheresis System or for replacement solutions of blood components removed.

PLEASE CONTACT HOSPITAL SERVICES TECHNICAL SPECIALIST FOR ANY UNLISTED SERVICES OR PROCEDURES