AGREEMENT BETWEEN
Clinton Hospital Authority
AND
THE OKLAHOMA BLOOD INSTITUTE

THIS AGREEMENT is entered into as of August 1, 2026, by Clinton Hospital Authority d/b/a Clinton Regional Hospital, 100 N. 30th Street, Clinton, OK 73601 ("Facility") and the Sylvan N. Goldman Center, Oklahoma Blood Institute, an Oklahoma not for profit corporation with its principal office located at 1001 North Lincoln Boulevard, Oklahoma City, OK, 73104 ("Blood Institute").

The Facility desires to utilize the services of the Blood Institute for the procurement of blood, blood components, and related services. The charges and fees payable to the Blood Institute for blood and blood components are to compensate the Blood Institute for its direct and indirect costs incurred for the administrative, medical, and technical services provided in the drawing, processing, storage, and delivery of blood or blood components; for donor recruitment; and for the maintenance of an inventory of blood and blood components (collectively, "blood services").

The Facility and the Blood Institute agree as follows:

1. Provision of Blood and Blood Components. During the term of this Agreement, the Facility will obtain from the Blood Institute all of the blood components required by the Facility in its daily operations, and the Blood Institute will supply all such blood components and services, subject to Paragraph 23 herein. These products and services are for the sole use of the Facility and will be utilized only within the Facility's facility at the address above and the Facility's affiliated facilities.

2. Processing and Services Fees. The Facility shall pay the Blood Institute the processing and services fees shown on the attached Schedule 2.0.

   2.1 Fee Increases. The Blood Institute, in its sole discretion, may increase the fees paid by the Facility during the term of this Agreement if one or more of the following should occur:

   (a) The U.S. Food and Drug Administration ("FDA") mandates, endorses, or licenses the implementation of a new test; or

   (b) Significant change occurs in the cost of compliance with blood banking industry standards, in either the technology used in product manufacturing, testing, or the offering of new products for patient use.

   2.2 Fees for Extended Term. The Blood Institute may increase the processing and services fees in each year (effective August 1) by up to five (5) percent, excluding the increased cost of any new test.

   2.3 Notice of Changes. The Blood Institute will provide the Facility with at least 30 days written notice of any changes to the fees payable under this Agreement.

3. Billing and Payment. The Blood Institute will provide an itemized monthly statement of charges to the Facility as of the last day of the month, unless the Facility has requested semi-monthly billing. Payment in full is expected no later than thirty (30) days from the date of the invoice. A prompt payment discount of 0.5% will be applied to all invoices paid within ten (10) days of the invoice date. A late penalty of 1.5% per month will be added to each invoice not paid within 30

days from the date of the invoice**.** At the Blood Institute's discretion, the late payment penalty may be suspended for a reasonable period of time in order to resolve any good faith disputes over payment.

3.1 In the event that the Facility has a previous Agreement with the Blood Institute, the Facility shall, within 15 days of the termination date of the Agreement, pay the Blood Institute any and all amounts owing for blood products and related services provided through the date of termination.

4. Sample Labeling Requirements. The Facility shall provide properly identified blood samples in sufficient volume to the Blood Institute for laboratory testing in accordance with the Blood Institute's Standard Operating Procedures (SOPs) and Association for the Advancement of Blood and Biotherapies (AABB) and FDA guidelines. The Blood Institute may refuse mislabeled samples and require the Facility to collect new, properly labeled samples. If multiple mislabeled samples are received from the Facility, the Blood Institute may suspend cross-matching services until the Facility can provide reasonably satisfactory written assurance to the Blood Institute that corrective action has been implemented.

5. Transfusion Records. A copy of the blood administration record (Bag Tag) documenting the transfusion of the product must be maintained at the facility in accordance with AABB and regulatory guidelines.

6. Delivery and Storage. It shall be the responsibility of the Facility to arrange with the Blood Institute for the pickup and delivery of blood samples and components. Once the components have left the Blood Institute's premises, it shall be the responsibility of the Facility to maintain the proper storage temperature of the components according to AABB and FDA guidelines.

6.1 The Facility shall store blood components only in a refrigerator that is approved for blood product storage. The Facility will monitor the storage unit and immediately notify the Blood Institute if any blood component has not been maintained at the appropriate temperature. The Facility will return such component in accordance with the Facility's SOPs.

6.2 If the Facility does not have a refrigerator that is approved for blood product storage, the blood components are to remain in the shipping container with the associated packing materials and the lid closed. Components are removed as they are needed. Once the need for the components is over, the Facility will return the components. The shipping container is validated to maintain temperature for 24 hours. The components must be returned within the 24 hour time window.

7. Peer Review. The Facility is responsible for the peer review of its transfusion practices. Upon request, the Blood Institute can provide transfusion related statistical data compilations for the Facility's review. If Facility is not able to perform peer review of its transfusion practices, the Blood Institute can provide this service.

8. Quality Standards and Regulatory Compliance. The Blood Institute shall maintain standards of performance consistent with its experience, research, and expertise in blood banking. Both parties shall maintain standards of performance in accordance with the applicable recommendations of the Center for Biologics Evaluation and Research (CBER) of the FDA, conform to the applicable requirements of all applicable state regulatory agencies, and comply with all other applicable laws, rules, and regulations. The Facility shall notify the Blood Institute as soon as practicable of any transfusion reactions resulting from the administration of any blood product it receives from the Blood Institute. The Facility shall maintain a record of the adverse reaction, conduct an investigation, and provide a completed Investigation of Suspected Transfusion Reaction Form (OBI-CL-FORM 255) to the Blood Institute, as required by 21 CFR

§606.170(a). Both parties shall comply with OSHA Bloodborne Pathogen Exposure Final Rule 29 CFR Part 1910.1030, effective March 2, 1996, and any subsequent revisions thereof. Compliance Statements are included in Schedule 8.0. All of the foregoing requirements are collectively referred to as the "Regulations." The Facility agrees that it will comply with the Quality Standards outlined in Exhibit B.

9. Records and Patient Information. The Facility will provide the Blood Institute with all transfusion records and patient information necessary for the provision of products and services under this Agreement. The parties will use and disclose protected health information in accordance with and as required by the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic & Clinical Health Act and the implementing regulations thereunder, as they may be amended from time to time (collectively, "HIPAA"), and will execute the Business Associate Agreement set forth in the attached Exhibit A. The Blood Institute will provide the Facility such information as may be required by the FDA for recommended guidelines about look back and product recalls.

10. OBI Medical Services.

10.1 The Blood Institute's medical directors shall have medical oversight over Blood Institute personnel who perform transfusion medicine-related activities and provide blood bank quality oversight on behalf of the Facility. The Blood Institute medical directors will provide interpretation of a suspected transfusion reaction based on laboratory evaluations as well as clinical information provided by the Facility. The Blood Institute's medical directors will not provide any direct patient care services; direct patient care duties are solely the responsibility of the clinical staff at the Facility.

10.2 Blood Institute will provide the Facility with clinician-to-clinician medical consultation services for transfusion-related issues and for recommendations regarding blood product utilization as requested and/or warranted.

10.3 The Blood Institute at its discretion will provide technical and transfusion education support under supervision of Blood Institute medical staff (web based or in person format) and maintain a section on the Blood Institute website dedicated to Transfusion services - https://ourbloodinstitute.org/hospital/. Transfusion services are strongly encouraged to participate in educational activities offered by or through the Blood Institute.

11. Indemnification.

11.1 The Blood Institute shall indemnify the Facility and its officers, directors, employees, and agents and hold each of them harmless from liability to and claims by third parties, including reasonable attorneys' fees, to the extent that they result from or arise in connection with the negligence or willful misconduct of the Blood Institute or its officers, directors, employees, or agents in the performance of this Agreement.

11.2 The Facility shall indemnify the Blood Institute and its officers, directors, employees, and agents and hold each of them harmless from liability to and claims by third parties, including reasonable attorneys' fees, to the extent that they may result from or arise in connection with the negligence or willful misconduct of the Facility or its officers, directors, employees, or agents in the performance of this Agreement.

12. Insurance. Each of the parties shall, at its own expense, maintain in effect a policy of professional liability insurance with coverage in the amount of not less than $1,000,000 per claim and $3,000,000 in aggregate. This coverage shall insure a party and its employees against liability for damages directly or indirectly related to the performance of any services and other respective obligations under this Agreement. Each party shall provide the other with a certificate from the insurance carrier evidencing the required coverage. With the Blood Institute's prior written consent, the Facility may opt to self-insure as to specifically identified risks. Each party shall notify the other of any adverse change in insurance coverage required by this Agreement.

13. Force Majeure. Neither party will be liable for any failure to perform its obligations (except payment obligations) for any reason beyond the party's reasonable control, including acts of terrorism, strikes, fires, explosion, flood, riot, lock out, injunction, interruption of transportation, unavoidable accidents, or a significant change in any applicable law or regulation.

14. Affirmative Action. The Blood Institute wishes to comply with the provisions of Executive Order 11246 of September 24, 1965; Executive Order 11375 of October 13, 1967; Executive Order 11758 of January 15, 1974; Section 503 of the Rehabilitation Act of 1973; the Vietnam Era Veterans Readjustment Act of 1974, as amended, 38 U.S.C. 4212 (formerly 2012); and the implementing regulations at 41 CFR Chapter 60. The Facility will not discriminate against any employee or applicant for employment because of race, color, religion, sex, national origin, handicap, or status as a disabled veteran or a veteran of the Vietnam Era. This policy to not discriminate in employment includes hiring, transfer, training during employment, and rates of pay.

15. Term. The term of this Agreement will begin August 1, 2026 and continue through July 31, 2031 (the "Initial Term"). After the Initial Term, the Agreement automatically renews from year to year (a "Successive Term") unless a Party provides written notice of termination at least thirty (30) days before the expiration of the Initial Term or any Successive Term. All terms and conditions of this Agreement shall remain in effect during any Successive Term. The Initial Term and any Successive Terms shall be referred to as the "Term". Processing and services fees may be adjusted each year as provided in Section 2.

16. Confidentiality. Both parties acknowledge that the terms, conditions, and fee schedules of this Agreement are confidential. This confidential information shall not be disclosed to any officer, director, employee, or agent of a party, except as necessary in carrying out the person's respective duties under this Agreement. This confidential information shall not be used other than in connection with this Agreement. Additionally, the parties shall keep confidential and not divulge to anyone else any of the proprietary, confidential information of the other party, including information relating to such matters as finances, methods of operation and competition, pricing, marketing plans and strategies, operational requirements, and information concerning personnel, referral sources, patients and suppliers.

17. Construction and Governing Law. The rule of construction that a document is to be construed most strictly against the party who drafted the document shall not be applicable because all parties participated in the preparation of this Agreement. "Includes" and "including" are not limiting. The laws of the State of Oklahoma shall govern this Agreement and the legal relations between the parties without giving effect to any conflict of law provision (whether of the State of Oklahoma or any other jurisdiction) that would cause the application of the law of any other jurisdiction.

18. No Assignment. Neither party may assign its rights or delegate its duties under this Agreement without the prior written consent of the other party; such consent shall not be unreasonably withheld.

19. No Third Party Beneficiaries. Nothing in this Agreement, express or implied, is intended to confer upon any person, firm, or corporation, other than the parties named herein, any right, remedy, or claim under or by reason of this Agreement, as third party beneficiaries or otherwise.

20. Termination. The Agreement may be terminated in the event that one or more of the following should occur: (a) by Blood Institute, without cause by providing a 60-day written notice to Facility; or (b) by reason of material breach, as provided below.

A Party may unilaterally terminate this Agreement (a) if the other Party fails to fulfill any one or more of its obligations under this Agreement ("Breach") and the Breach continues for a period of thirty (30) days after the non-breaching Party sends written notice of the Breach; (b) if any of the Regulations are amended in a way that precludes a Party from performing its obligations under this Agreement, effective upon the effective date of the amended Regulation; (c) if a Party ceases to operate or otherwise function as a business; (d) if a Party fails to maintain professional liability insurance as required herein; (e) if a Facility fails to address items documented on the Transfusion Service Remediation Request form (provided in **Exhibit C**) within the appropriate timeframe (e.g., failure to implement blood safety recommendations provided by Blood Institute medical or laboratory staff based upon onsite inspection/assessment findings); or (f) if Facility does not meet established annual blood drive collections goals provided in Section 30 or mutually agreed upon alternative Blood Donor Recruitment Standards following annual review.

The Blood Institute may unilaterally terminate this Agreement upon notice to the Facility if (x) the Facility's state license to operate as a hospital is suspended, terminated, or revoked by the State Department of Health, or (y) the Facility is excluded from participation in Medicare, Medicaid, or any other federal health care program. Termination of this Agreement pursuant to this provision shall not constitute an election of remedies, and the terminating party shall retain all rights and remedies that may be available at law or in equity with respect to the default by the other party. Upon termination, the Facility shall, within 15 days of the termination date, pay the Blood Institute any and all amounts owing for blood products and related services provided through the date of termination.

21. Entire Agreement; Amendments; Waiver. This Agreement is the final expression of the entire agreement of the parties. This Agreement supersedes all prior agreements and understandings between the parties. This Agreement may not be amended, modified, or waived except by a written agreement designated as such and signed by the party against whom it is to be enforced. The failure of a party to insist upon the strict observance or performance of any of the provisions of this Agreement or to exercise any right or remedy shall not impair any such right or remedy or be construed as a waiver or relinquishment thereof with respect to subsequent defaults.

22. Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will constitute one and the same Agreement. The exchange of copies of this Agreement and of signature pages by facsimile transmission shall constitute effective execution and delivery of this Agreement and may be used in lieu of the original Agreement for all purposes.

23. Inventory Control. If applicable, a minimum standing inventory of transfusable blood products will be agreed upon between the Blood Institute and the Facility. In keeping with accepted transfusion practice, Red Blood Cell (RBC) product inventory may include one or more O Rh-positive RBC units and/or units of other blood types. Limitations on Facility O Rh-negative inventory or supply may be applied by the Blood Institute in times of O-Rh negative RBC availability constraints. Such inventory shall be maintained at the Facility by the Blood Institute on a consistent basis, in the amount and variety of RBC unit types and blood components necessary to meet the routine needs of the Facility. The Facility will promptly notify the Blood Institute of any requests for specialized

blood products, services, or variations to the Facility's standing inventory. Such requests may be subject to the Blood Institute's medical review and approval.

24. Credit/Return Policy (if applicable). Regular communication between the Facility and the Blood Institute must occur to prevent the expiration and destruction of blood or blood components. Credit will only be issued in accordance with the guidelines stated on the attached Credit/Return Policy, Schedule 24.0. The Blood Institute may modify the Credit/Return policy during the term of this Agreement by giving 30-days written notice to the Facility.

25. Donor Source. Only blood donations from volunteer donors will be utilized in the preparation of blood products for transfusion.

26. Charges by Facility. The Facility fees provided in this Agreement are intended to defer the Blood Institute's previously described operational costs. This Agreement does not restrict the Facility's ability to add service charges as it deems reasonable and prudent to ensure proper patient service and as may be permitted by applicable law.

27. Notice. Any notice, consent, or communication required or permitted to be given under this Agreement shall be deemed to have been duly given if in writing and delivered personally, sent by electronic transmission, or sent by United States first class mail, postage prepaid, to the addresses set forth in the introduction of this Agreement.

28. Binding Effect. This Agreement shall be binding upon, and inure to the benefit of, the parties and their respective legal representatives, successors, and assigns.

29. Survivability of Terms. The terms and provisions and each party's obligations and/or agreements under Sections 9, 11, and 16 shall survive any termination or expiration of this Agreement and will be construed as agreements independent of any other provisions of this Agreement.

30. Communications and Community Relations. The Facility plays a critical role in the Blood Institute's ability to support the Facility with blood products, and the Facility desires to assist the Blood Institute in its efforts. The Facility can accomplish this objective by encouraging community support of the Blood Institute. Through the use of its public relations and communications efforts, the Facility can encourage the public to make blood donations to the Blood Institute. In communities where the Blood Institute is the new blood provider, the Facility can help to introduce the Blood Institute to the community as the blood provider. In furtherance of these goals, the Facility will issue news releases to the local media announcing the Blood Institute as the provider of blood and blood products. The news releases will advise Facility staff of the collaboration between the Facility and the Blood Institute to ensure that the Facility staff is knowledgeable and supportive of the relationship. The Facility shall allow the Blood Institute to place approved printed materials in strategic locations within the Facility (*e.g.*, in lobbies, waiting rooms, *etc.*) stating the Blood Institute is the blood provider and encouraging blood donations. From time to time, the Facility may have the appropriate persons in Facility administration send communications to community leaders (*e.g.*, business leaders, ministers, school superintendents, civic group leaders, governmental leaders, *etc.*) encouraging personal and group support of blood donations to the Blood Institute. The Facility may provide ongoing support for the Blood Institute with the media, the Facility, and the community. The Blood Institute will provide staff and resources to assist with any or all of the Facility's public relations efforts on behalf of the Blood Institute. **The Facility agrees to encourage blood donations and to assist Blood Institute personnel and the Facility's Blood Drive Coordinator in efforts to procure blood and components within the Facility's service area. Any blood drives held on the Facility's premises will be conducted by and for the Blood Institute. The Facility will host or co-sponsor a minimum of four (4) blood drives with minimum collections totaling 40 units annually, unless Parties mutually agree upon alternative Blood Donor Recruitment Standards.**

31. Review of Service Performance Indicators. The Facility is solely responsible for monitoring service provided by the Blood Institute in the following areas:

a. Laboratory Transfusion Service Turnaround Time (TAT). Transfusion Service testing turnaround time begins upon receipt of the sample into the Blood Institute Reference Lab.

STAT	2-4 hours from sample receipt (does not include transportation time)
ASAP	5-8 hours from sample receipt (does not include transportation time)
ROUTINE	8-24 hours from sample receipt (does not include transportation time)

If complex testing is required, including but not limited to multiple antibodies or warm or cold autoantibodies, the laboratory turnaround times above do not apply but testing will be completed as soon as possible. Reasonable effort will be made to communicate delays related to case/specimen complexity with the Facility.

Total Turnaround Time. The Blood Institute makes no claims to total turnaround time, from physician order to product transfusion, as total turnaround time is influenced by Facility specimen acquisition, transportation, laboratory testing time, Facility blood administration and product release to patient by Facility staff.

b. Billing Accuracy. Billing and coding of monthly invoices from the Blood Institute will be reviewed for accuracy.

c. Compliance with Standards and Regulations. The Parties will comply with accreditation standards and regulatory requirements affecting the Facility in the performance of the Agreement.

FOR: THE FACILITY

_____
Signature

_____
Date

_____
Print Name

_____
Print Title

FOR: THE BLOOD INSTITUTE

_____
John Armitage, M.D., President and CEO

_____
Date

Schedule 8.0
COMPLIANCE STATEMENTS

The Oklahoma Blood Institute (OBI) manufactures Blood and Blood Products under Food and Drug Administration (FDA) license number 0766. Each OBI facility has an FDA assigned Establishment Identification Number (FEIN) and is inspected by the FDA to evaluate current Good Manufacturing Practices (cGMP) and compliance with relevant sections of 21 CFR 200, 600, 800 and 1200.

Association for the Advancement of Blood and Biotherapies (AABB) Blood Banks and Transfusion Services accreditation is maintained by OBI. In accordance with the Social Security Act and 42 CFR Parts 422.156, 422.157, and 422.158, the Centers for Medicare and Medicaid Services (CMS) has granted AABB deemed status to provide oversight for compliance with the Clinical Laboratory Improvement Amendments (CLIA). Therefore, AABB standards have been found to meet or exceed all relevant CMS requirements for participation. AABB bi-annual assessments evaluate OBI against these standards.

Infectious Disease Testing is provided under CLIA number 37D0470358 and Immunohematology Testing is provided under CLIA number 37D2175055 in the headquarters location in Oklahoma City. Immunohematology Testing is also provided under CLIA number 37D0931105 in the Tulsa location, CLIA number 04D2096885 in the Little Rock location, and CLIA number 45D0507042 in the Coffee Memorial Blood Center location. CLIA compliance inspections and renewals are performed bi-annually by the AABB. OBI Laboratories participate in CMS approved proficiency testing programs. AABB Immunohematology Reference Laboratory Accreditation is maintained by the Clinical Laboratory in Oklahoma City.

OBI maintains a Quality Plan, Quality Manual, Emergency Preparedness and Disaster Plan, Transfusion Associated Disease Investigation Procedures, Look-Back Procedures (HCV and HIV), and Consignee Notification Procedures for Positive Test Results, Market Recalls and Market Withdrawals for non-conforming blood or blood components. Initial consignee notifications occur in accordance with federal and state statutes and regulations. Specifically, they occur within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection; within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available; and within 45 days of the test, of the results of the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by FDA. These documents can be made available for reference during relevant facility inspections.

Except for apheresis platelets treated using an FDA-approved pathogen reduction process, OBI performs bacterial detection testing on all apheresis platelet components. This test is a culture that is incubated throughout the shelf life of the product. If a unit tests positive on the BACT/ALERT VIRTUO Microbial Detection System after shipment, OBI will notify consignees of the affected product.

OBI maintains a Privacy Policy and Business Associate Agreements that include relevant requirements identified in 45 CFR 164, Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the Information Technology for Economic and Clinical Health (HITECH) Act of 2009.

<u>For Regulatory or Compliance Issues, Call</u>
VP, Quality Management (405) 297-5527
Compliance Officer (405) 297-5733

Schedule 24.0
BLOOD PRODUCTS CREDIT/RETURN POLICY
OKLAHOMA BLOOD INSTITUTE

The following blood products may be returned for credit or exchange to the Oklahoma Blood Institute in accordance with the following established guidelines:

Product	**Timeframe**
	Restrictions required to receive credit:
LEUKOREDUCED RED CELLS	a. Stored at 1 to 6 degrees Centigrade as documented by a continuous recording device;
	b. The blood container has neither been entered nor its closure disturbed;
	c. Product storage has met all other applicable CBER/FDA and AABB requirements;
	d. At least one crossmatch segment remains attached; and
	e. Greater than 7 days of shelf life remain before the product outdates/expires.
LEUKOREDUCED PLATELETS (Single donor) (Apheresis-derived)	Greater than 24 hours of shelf life, providing such products have been: a. Stored at 20 to 24 degrees Centigrade as documented by a continuous recording device; b. Stored with continuous agitation; and c. The blood container has neither been entered nor its closure disturbed.
	If less than 24 hours of shelf life, OBI will assist the Facility in offering the product to another facility [provided products also meet the requirements above]. If successful, credit will be issued to the Facility; if unsuccessful, credit will not be issued. *This policy provision will not apply where the product had 48 hours or less of remaining shelf life when supplied to the Facility by OBI.*
PLASMA and PLASMA PRODUCTS	Plasma and Plasma products will not be accepted for credit.
MODIFIED PRODUCTS	Products modified by the Blood Institute or the Facility will not be accepted for credit, including thawed plasma and plasma products.
AUTOLOGOUS UNITS	No returns will be accepted/credited.

The Blood Institute may request product returns for investigation of visual issues and/or clots. The Facility will tag units returned for evaluation with Quarantine tags provided by Blood Institute. If a product has been thawed at Facility, the product shall be returned thawed, as refrozen products can impede product evaluation. The Blood Institute may request that the Facility provide a photo of the unit prior to return. Units returned for investigation will be subject to the Blood Institute's review and approval for credit.

Exhibit A
BUSINESS ASSOCIATE AGREEMENT

THIS AGREEMENT is entered into as of August 1, 2026, by Clinton Hospital Authority d/b/a Clinton Regional Hospital, 100 N. 30th Street, Clinton, OK 73601 ("Facility") and the Sylvan N. Goldman Center, Oklahoma Blood Institute, an Oklahoma not for profit corporation with its principal office located at 1001 North Lincoln Boulevard, Oklahoma City, OK, 73104 ("Blood Institute").

A. The Blood Institute provides services for the procurement of blood and blood components and related services (the "Services") for the Facility pursuant to a written agreement between the parties (the "Services Agreement").

B. The Blood Institute and the Facility are subject to the privacy and security requirements of the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic & Clinical Health Act, and the implementing regulations promulgated thereunder, as amended from time to time (collectively, "HIPAA").

C. To facilitate the provision of Services by the Blood Institute, it may be necessary for the Facility to disclose protected health information concerning its patients to the Blood Institute. "Protected health information" is demographic information collected from a patient which (a) is created or received by the Facility, (b) relates to the past, present, or future physical or mental health condition, the provision of health care or the past, present, or future payment for the provision of health care of a patient, and (c) identifies the patient, or the information can be used to identify the patient. "Protected health information" includes information that is transmitted, maintained, or received electronically. Demographic information that identifies the patient or that could be used to identify a patient includes: name, street address, city, county, precinct, zip code, birth date, admission date, discharge date, date of death, telephone number, fax number, email address, social security number, medical record number, health plan beneficiary number, account number, certificate/license numbers, vehicle identifier and serial number, and full face photographic images and any comparable images.

D. The Facility wishes to obtain satisfactory assurances from the Blood Institute that the Blood Institute will safeguard protected health information from misuse and unauthorized disclosure and that the Blood Institute will assist the Facility in complying with other requirements related to protected health information.

In consideration of the covenants, terms, and conditions set forth in this Agreement, the Facility and the Blood Institute agree as follows:

1. Protected Health Information. The Blood Institute and the Facility shall appropriately safeguard from misuse and unauthorized disclosure all data that is protected health information.

2. Business Associate Standards. By virtue of this Agreement, the Blood Institute may receive protected health information on behalf of Facility and is thereby subject to the "business associate" standards set forth herein. The Blood Institute may use and disclose protected health information it receives from the Facility, in accordance with HIPAA, strictly for the following purposes, and only to the extent necessary for the Blood Institute to perform its obligations under the Services Agreement:

a. The Blood Institute may use and disclose protected health information it receives from the Facility (i) in the proper management and administration of the Blood Institute; (ii) as required by law; (iii) to carry out its legal responsibilities; (iv) to perform blood banking and transfusion services in accordance with recognized standards of care; or, (iv) to other person(s) who provide reasonable written assurances that the information will be held confidentially, under the same conditions and restrictions that apply to the Blood Institute, and used or further disclosed only as required by law or for the purpose for which it was disclosed to such person, and that such person(s) will notify the Blood Institute of any instances which it is aware or becomes aware that the confidentiality of the information has been breached;

b. The Blood Institute may use and disclose protected health information it receives from the Facility to provide data aggregation services relating to the health care operations of the Facility;

c. The Blood Institute may use and disclose protected health information it receives from the Facility for purposes related to the testing and analysis of specimens and for internal operational purposes, including: conducting quality assessment and improvement activities; conducting or arranging for medical review, legal services, or auditing functions; business planning, development, and management; implementing and conducting compliance programs; performing aggregate data analysis; research; and conducting due diligence in connection with the sale of part or all of the business.

d. With respect to information that it has received from Facility, the Blood Institute shall:

   (i) Not use or further disclose the information other than as permitted or required by this Agreement or as required by law; not copy, duplicate or otherwise reproduce any part of the information except as required to perform services under the Services Agreement; and comply with the HIPAA privacy regulations with respect to any obligations under HIPAA that the Blood Institute is performing on behalf of the Facility;

   (ii) Promptly report to the Facility if the Blood Institute becomes aware of any use or disclosure of protected health information not permitted by this Agreement or any other security incident related to the protected health information, and take all necessary actions to promptly remedy the situation and to minimize any adverse consequences of such use, disclosure, or security incident;

   (iii) Ensure that any agents, representatives, subcontractors, or others to whom the Blood Institute provides protected health information received from, or created or received by the Blood Institute on behalf of the Facility (each, a “Subcontractor”) enters into a written agreement with the Blood Institute that imposes the same obligations on the Subcontractor that are imposed on the Blood Institute under this Business Associate Agreement;

   (iv) Make available protected health information in accordance with 45 CFR 164.524;

(v) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with 45 CFR 164.526;

(vi) Make available the information required to provide an accounting of disclosures in accordance with 45 CFR 164.528;

(vii) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the Blood Institute on behalf of the Facility, available to the Secretary of the Department of Health and Human Services for purposes of determining the Facility's compliance with 45 CFR 164.500 – 534; and,

(viii) At termination of this Agreement, if feasible, return, destroy, or permanently delete all protected health information received from, or created or received by the Blood Institute on behalf of the Facility that the Blood Institute still maintains in any form and retain no copies of such information, except (A) the Blood Institute may retain, use, and disclose such protected health information to meet quality standards and public health and regulatory requirements related to its blood banking and transfusion services, or (B) the Blood Institute may retain such protected health information if return or destruction is not feasible and the Blood Institute extends the protections of this Agreement to retained information and limits further uses and disclosures to the purposes that make return or destruction infeasible.

e. The Facility shall be responsible for obtaining all consents and authorizations of patients, in accordance with HIPAA.

3. Use of Safeguards. The Blood Institute shall use appropriate safeguards to prevent the use or disclosure of the protected health information other than as provided for by this Agreement. If protected health information is transmitted, maintained, or received electronically, the Blood Institute shall use administrative, technical, and physical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of such information, including access controls, workstation security, integrity controls, data backup, and storage and encryption.

4. Reporting. The Blood Institute shall promptly report to the Facility not later than 30 days after the Blood Institute becomes aware of (a) any acquisition, access, use, or disclosure of protected health information not permitted by this Agreement or HIPAA, or (b) any other security incident related to protected health information of which the Blood Institute becomes aware (an "Incident") whether or not the Incident qualifies as a "reportable breach" under HIPAA. With respect to a reportable breach, the Blood Institute shall provide the following information to the Facility: (a) a brief description of the Incident; (b) a description of the nature and extent of protected health information involved in the Incident; (c) the individual who impermissibly used the protected health information; (d) a description of the Blood Institute's actions to mitigate the consequences of the Incident and to prevent further Incidents; and (e) if requested by the Facility, contact procedures for individuals to contact the Blood Institute for additional information. Except as directed by the Facility, the Blood Institute shall not directly report an Incident to the Secretary, the media, or any individual, and shall keep the matter strictly confidential. The parties shall take all necessary actions to promptly remedy the situation and to minimize any adverse consequences of such Incident.

5. Independent Contractor Status. The Blood Institute is performing services for the Facility as an independent contractor. Nothing in this Agreement shall be construed as creating an agency, partnership, employment, or joint venture relationship between the Blood Institute and the Facility. Neither party may bind, or create any obligations on behalf of, the other party.

6. Obligation to Disclose Information. This Agreement does not impose any specific obligations on the Facility to disclose protected health information.

7. Binding Effect. This Agreement shall be binding upon the parties hereto and their respective legal representatives, successors, and assigns.

8. Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Oklahoma.

9. Assignment. This Agreement may not be assigned by the Blood Institute, nor may the Blood Institute delegate its duties hereunder, without the express prior written consent of the Facility.

10. Amendments. This Agreement may not be amended except by an instrument in writing signed by the Facility and the Blood Institute.

11. Notices. Any and all notices, consents, or other communications by one party intended for the other shall be deemed to have been properly given if in writing and personally delivered, transmitted by electronic means, or deposited in the United States, postpaid, to the addresses or numbers set forth below the signatures of the parties.

12. No Waiver. No waiver of a breach of any provision of this Agreement shall be construed to be a waiver of any breach of any other provision. No delay in acting with regard to any breach of any provision of this Agreement shall be construed as a waiver of such breach.

13. Entire Agreement. This Agreement constitutes the entire understanding and agreement of the parties with respect to its subject matter and cannot be changed or modified except by another agreement in writing signed by the parties.

EXECUTED as of the date written above.

FOR: THE FACILITY	**FOR: THE BLOOD INSTITUTE**
_____	_____
Signature	John Armitage, M.D., President and CEO
_____	_____
Date	Date
_____	
Print Name	
_____	
Print Title	

Exhibit B
Quality Standards

The Facility, through its employees, agents or consultants, agrees to be solely responsible for performing and documenting these quality requirements. Additionally, the Facility agrees to provide the Blood Institute with documentation of compliance, when requested by the Blood Institute.

1. The Facility agrees that it will use only trained individuals to perform sample collections, patient consents, and blood transfusions. The Facility further agrees to annually assess and document the competency of these individuals as required by federal law in 42 CFR 493.1235 and 42 CFR 493.1451.

2. The Facility agrees to maintain a list of the employees, agents, or consultants, identifiers or initials used by the Facility to track those responsible for collecting samples, consenting patients, or performing transfusions. This list will contain the inclusive dates of employment.

3. The Facility agrees that blood or blood products will only be stored in a validated storage device or container, that the device will be continuously monitored and equipped with an alarm system, and to notify the Blood Institute of temperature excursions.

4. The Facility agrees to develop and administer transfusion consent forms that adequately describe risks associated with transfusions and to utilize the transfusion service physician or designee as a resource in identifying and describing the associated risks.

FOR: THE FACILITY

_____
Signature

_____
Date

_____
Print Name

_____
Print Title

FOR: THE BLOOD INSTITUTE

_____
John Armitage, M.D.
President and CEO

_____
Date

Exhibit C
Transfusion Service Remediation Request

Facility Name:	
Reason for Remediation Request:	
☐Financial - Section 3, Billing and Payment - 30 days	☐ Contractual/Other: - Section 20, Termination - 30 days

Description of Issue or Area of Concern:

_____

_____

_____

_____

Remediation Request Details:

_____

_____

_____

_____

_____

Requested remediation should be completed within the timeframe noted above.

Name/Title of Person Notified at the Transfusion Service Facility:

_____

Method of notification (Certified Mail, Email, Fax, Phone):

_____

Date and Time of Notification: _____

Form Completed by: _____

Date of Completion: _____

Attach any additional documentation to this form.