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## BLOOD BANKS, TISSUE BANKS, AND ORGAN PROCUREMENT SUPPLEMENTAL APPLICATION

COMPLETE IN ADDITION TO ACORD APPLICATIONS.

ATTACH ADDITIONAL SHEETS AS NECESSARY.

ANSWER ALL QUESTIONS. If not applicable, indicate N/A.

### GENERAL INFORMATION

1)

Named Insured:			
Additional Named Insureds:			
Brokerage/Broker:			Agency/Agent:
Effective Date:			
Website:			

2)

Carrier:			
Limit of Insurance:			
Deductible:			Premium:
Policy Term Dates:			
Offering renewal? Yes <input type="checkbox"/> No <input type="checkbox"/>	Claims made? Yes <input type="checkbox"/> No <input type="checkbox"/>	Retroactive date:	

Please attach copies of the following:

- Currently valued five year loss runs, including claim detail for all losses open or exceeding \$15,000
- Your brochures, advertisements, or marketing materials if a website is not available
- A copy of your current financial statement, including balance sheet and income statement
- A copy of your expiring policy Declarations page for retroactive date and limits continuity
- A copy of your last FDA, regulatory authority, or accreditation inspection report
- A copy of your Informed Consent documents
- A copy of your complete, detailed written processing, quarantine, and testing procedures and protocols.

3) Mailing Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

4) Premise Address #1 (if different from above): \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_ FDA License: \_\_\_\_\_

5) Premise Address #2: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_ FDA License: \_\_\_\_\_

6) Premise Address #3: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_ FDA License: \_\_\_\_\_

- 7) Are you a(n):  Corporation  Individual  Partnership  LLC  
 Joint Venture  Other: \_\_\_\_\_
- 8) Your enterprise is:  
 For Profit  Not for Profit  Other: \_\_\_\_\_
- 9) Audit/Inspection contact: \_\_\_\_\_  
a. Phone number: \_\_\_\_\_  
b. Email: \_\_\_\_\_

### OPERATIONAL INFORMATION

10) What are your operations? \_\_\_\_\_  
\_\_\_\_\_

11) Please complete the below table regarding your revenues and donors:

	Upcoming Year (est.):	Last 12 Months:	One Year Prior:	Two Years Prior:	Three Years Prior:
<b>Revenues</b>					
<b>Donors</b>					

12) Please complete the following for your donor sourcing:

Donor Source:	Percentage of Donors Upcoming Year (est):	Percentage of Donors Last Year:
Paid Donations		
Volunteer Donations		
Autologous Donations		
Foreign Donations		
Pheresis Donations		
Postmortem Donations		
Other: _____		
<b>TOTAL:</b>	<b>100%</b>	<b>100%</b>

13) Please complete the following for your donated, procured, or banked materials:

Material:	Percentage Upcoming Year (est):	Percentage of Last Year:
Blood		
Tissue		
Organs		
Cord Blood		

Sperm		
Eggs		
Embryos		
Bone Marrow		
Other: _____		
<b>TOTAL:</b>	<b>100%</b>	<b>100%</b>

- 14) Do you offer mobile blood units or similar off-premises services? Yes  No
- a. If yes, please attach a copy of your contract.
- b. On average, how many annual events do you have? \_\_\_\_\_
- c. On average, how many annual donors participate at these events? \_\_\_\_\_
- 15) Do you conduct any research activities? Yes  No
- a. If yes, please attach details.
- 16) Do you source any blood, tissues, or organs from other than human sources? Yes  No
- a. If yes, are these materials veterinary or research use only? Yes  No
- b. If no to a., please attach details.
- 17) Are you a member of any of the following accreditation or industry trade organizations? Check all that apply:
- Accredited by the American Association of Blood Banks
- Accredited by the American Association of Tissue Banks
- Accredited by the Foundation for the Accreditation of Cellular Therapy (FACT)
- Member of the American Blood Center
- Member of the American Society for Transplantation and Cellular Therapy (ASTCT)
- Member of the International Society for Cell & Gene Therapy (ISCT)
- Other: \_\_\_\_\_
- Other: \_\_\_\_\_

### TESTING AND QUALITY CONTROL INFORMATION

- 18) What date did you begin continuous testing for HIV? \_\_\_\_\_
- 19) What date did you begin continuous testing for HTLV-I? \_\_\_\_\_
- 20) Is testing performed by a contracted third party? Yes  No
- a. If yes, do you collect Certificated of Insurance from these subcontractors? Yes  No
- b. Are you listed as an Additional Insured on these policies? Yes  No
- c. What minimum limits do you require? \_\_\_\_\_
- 21) Do you perform testing services for other facilities? Yes  No
- a. If no, what is the average annual revenue from these operations? \_\_\_\_\_
- b. Do you have a written contract in place with these facilities? Yes  No
- 22) Do you have a formal written internal quality control and testing program? Yes  No
- a. If yes, confirm how long these records are maintained: \_\_\_\_\_
- b. Do you have a full time risk manager? Yes  No
- c. How frequently do you audit your procedures? \_\_\_\_\_

d. How often do you perform maintenance on equipment? \_\_\_\_\_

23) When was your last FDA, regulatory authority or accreditation organization inspection? \_\_\_\_\_

**STAFF**

24) Please complete the following for your staff:

	Number Employed		Number Contracted	
	Full-Time	Part-Time	Full-Time	Part-Time
Medical Director				
Physician				
RN, LPN				
CRNA				
Nurse Practitioner				
Phlebotomist				
Technician				
Compliance/QA				
Other: _____				

25) Are all of the individuals included in the table above licensed in accordance with applicable State and Federal regulations? Yes  No

26) Do you require all sales and service personnel to participate in a formal program that instructs them on all applicable company policies, procedures, and training? Yes  No

27) Which of the following procedures do you use for hiring/screening employees? Check all that apply:

- Check of educational background
- Check of previous employers – In writing
- Criminal background check – State
- Driver’s license verification
- Drug screening
- Abuse screening
- Verification of license validity, suspensions, revocations, citations, or pending disciplinary actions
- Verification of any pending disciplinary actions by current or previous employers
- Other: \_\_\_\_\_
- Check of residency program
- Check of previous employers – By telephone
- Criminal background check – Federal
- MVR Check
- Alcohol screening
- Reference verification

**COVERAGE AND LOSS HISTORY**

28) Have you been inspected by the FDA in the last five years? Yes  No   
 a. If yes, please list dates: \_\_\_\_\_

b. Were you issued an FDA 483 form? *If yes, please attach copies as well as your response.* Yes  No

29) Have any adverse events concerning your products been reported to you or the FDA in the last Yes  No

five years?

a. If yes, how many? \_\_\_\_\_

b. Please attach a description of product and adverse event details, responses, investigations or testing, etc. in response to these events.

30) Have you been cited by any regulatory agency for violations arising out of business activity involving your product(s)? If yes, please provide details: \_\_\_\_\_ Yes  No

31) Have you had Liability insurance continuously for the last five years? Yes  No

a. If yes, please complete the below table for your four prior carriers:

Insurer	Dates covered	Limits of Liability	Deductible	Premium	Retroactive date

32) Have you had any Liability claims that were or were not covered by insurance? Yes  No

**If yes, please attach an explanation.**

33) During the past five years, has any insurer ever canceled or non-renewed similar insurance to any applicant or has your insurance been canceled for nonpayment of premium by any insurance or finance company? If yes, please attach an explanation. Yes  No

34) Is your company aware of any occurrences, facts, circumstances, incidents, situations, damages or accidents arising out of or related to your operations that a reasonably prudent person might expect to give rise to a claim or lawsuit whether valid or not which might directly or indirectly involve the company? If yes, please attach an explanation. Yes  No

**FRAUD WARNING**

**NOTICE TO ALABAMA, ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, CONNECTICUT, DELAWARE, GEORGIA, IDAHO, ILLINOIS, INDIANA, IOWA, KANSAS, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NEVADA, NEW HAMPSHIRE, NORTH CAROLINA, NORTH DAKOTA, OREGON, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TEXAS, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA, WISCONSIN, AND WYOMING APPLICANTS:** In some states, any person who knowingly, and with intent to defraud any insurance company or other person, files an application for insurance or statement of claim containing any materially false information, or, for the purpose of misleading, conceals information concerning any fact material thereto, may commit a fraudulent insurance act which is a crime in many states.

**NOTICE TO COLORADO APPLICANTS:** It is unlawful to knowingly provide false, incomplete or misleading facts or information to an insurance company for the purpose of defrauding or attempting to defraud the company. Penalties may include imprisonment, fines, denial of insurance and civil damages. Any insurance company or agent of an insurance company who knowingly provides false, incomplete or misleading facts or information to a policy holder or claimant for the purpose of defrauding or attempting to defraud the policyholder or claiming with regard to a settlement or award payable for insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

**NOTICE TO DISTRICT OF COLUMBIA APPLICANTS: WARNING:** It is a crime to provide false or misleading information to an insurer for the purpose of defrauding the insurer or any other person. Penalties include imprisonment and/or fines. In addition, an insurer may deny insurance benefits if false information materially related to a claim was provided by the applicant.

**NOTICE TO FLORIDA APPLICANTS:** Any person who knowingly and with intent to injure, defraud or deceive any insurance company files a statement of claim containing any false, incomplete or misleading information is guilty of a felony of the third degree.

**NOTICE TO HAWAII APPLICANTS:** For your protection, Hawaii law requires you to be informed that presenting a fraudulent claim for payment of a loss or benefit is a crime punishable by fines or imprisonment, or both.

**NOTICE TO KENTUCKY APPLICANTS:** Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance containing any materially false information or conceals, for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime.

**NOTICE TO LOUISIANA APPLICANTS:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

**NOTICE TO MAINE APPLICANTS:** It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties may include imprisonment, fines, or denial of insurance benefits.

**NOTICE TO NEW JERSEY APPLICANTS:** Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

**NOTICE TO NEW MEXICO APPLICANTS:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to civil fines and criminal penalties.

**NOTICE TO NEW YORK APPLICANTS:** Any person who knowingly and with intent to defraud an insurance company or other person files an application for insurance or statement of claim containing any materially false information, or conceals, for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime and shall also be subject to a civil penalty not to exceed \$5,000 and the stated value of the claim for each such violation.

**NOTICE TO OHIO APPLICANTS:** Any person who, with intent to defraud or knowing that he/she is facilitating a fraud against an insurer, submits an application or files a claim containing a false or deceptive statement is guilty of insurance fraud.

**NOTICE TO OKLAHOMA APPLICANTS: WARNING:** Any person who knowingly, and with intent to injure, defraud or deceive any insurer, makes a any claim for the proceeds of an insurance policy containing any false, incomplete or misleading information is guilty of a felony.

**NOTICE TO PENNSYLVANIA APPLICANTS:** Any person who knowingly and with intent to defraud any insurance company, or other person, files an application for insurance or statement of a claim containing any materially false information or conceals for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects the person to criminal and civil penalties.

**NOTICE TO TENNESSEE APPLICANTS:** It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

**NOTICE TO VIRGINIA APPLICANTS:** It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

**The Applicant acknowledges that the answers provided herein are based on a reasonable inquiry and/or investigation. The Applicant warrants that the above statements and particulars together with any attached or appended documents are true and complete and do not misrepresent, misstate or omit any material facts.**

**The Applicant agrees to notify us of any material changes in the answers to the questions on this questionnaire which may arise prior to the effective date of any policy issued pursuant to this questionnaire and the Applicant understands that any outstanding quotations may be modified or withdrawn based upon such changes at our sole discretion.**

**Completion of this form does not bind coverage. Applicant's acceptance of the company's quotation is required prior to binding coverage and policy issuance.**

**All written statements and materials furnished to the company in conjunction with this application are hereby incorporated by reference into this application and made a part of this application.**

Applicant: \_\_\_\_\_ Title: \_\_\_\_\_

FEIN #: \_\_\_\_\_

Applicant's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Agent/Broker Name: \_\_\_\_\_