Kinsale Insurance Company
P. O. Box 17008
Richmond, VA 23226
(804) 289-1300
www.kinsaleins.com

APPLICATION FOR TISSUE BANKS, BLOOD BANKS AND ORGAN PROCUREMENT

Instructions to the Applicant – please complete this application in ink and answer all questions completely.

Attach extra sheets as necessary should you run out of space provided. An incomplete or illegible application cannot be processed. Completion of this application neither binds coverage nor guarantees that a policy will be issued.

Provide a fully completed application, signed and dated by the owner, partner, or officer not earlier than 45 days before the proposed effective date of coverage.

If a question is not applicable, then state "N/A".

The following information must be submitted with the completed application:

- Copy of your current professional liability insurance Declarations Page (claims made policies must reflect the retroactive date)
- Copy of your Informed Consent documents
- Copy of all contracts between you and any Principal Investigators or trial sponsors
- Copy of your advertisements
- Copy of your current Financial Statement
- 5-year company loss runs, valued within the last 60 days

GENERAL INFORMATION

Applicant Name:____

List of Any Previous Names or Organizations:____

Date Established:______________________________ Website:____

Mailing Address:____

Additional Locations: ____

____

____

Applicant is: ☐ Corporation ☐ Partnership ☐ Joint Venture ☐ Not For Profit ☐ Limited Liability Company ☐ Individual ☐ Other

Audit Contact: __________________________________ Phone Number: ____________________________________

Description of Operations:____

____

____

____

Locations

Name and Address	Description	Retro Date	FDA License

Revenues and Anticipated Number of Donors

	Revenues	Donors
Upcoming Year	________________	________________
Current Year	________________	________________
First Prior Year	________________	________________
Second Prior Year	________________	________________
Third Prior Year	________________	________________

STAFFING

1. Please indicate the number of employed professionals or independent contractors

Staff:	Full Time	Part Time	Contracted
Medical Director			
Physician			
RN/LPN			
Nurse Practitioners			
Phlebotomist			
Technicians			
Compliance/QA			
Other (specify)			

Check the hiring procedures that apply or are performed:

☐ Criminal Background Checks

☐ Drug, alcohol and sexual abuse screening or testing

☐ Verification of certification or professional licensing

☐ Reference Checks

☐ Questioning of employees in their previous involvement as defendants in professional malpractice litigation.

SERVICES

1. Annual Exposure (Percentage)

Paid Donations ________________

Volunteer Donations ________________

Autologous Donations ________________

Foreign Donations ________________

Pheresis Donations ________________

Postmortem Donations ________________

2. Annual Exposure (Percentage)

Blood ________________

Tissue ________________

Organ ________________

Cord Blood ________________

Sperm ________________

Embryo ________________

Bone Marrow ________________

Other (describe): ________________

OPERATIONS

1. List all of the applicable accreditation or industry trade organization memberships:
   - ☐ Accredited by the American Association of Blood Banks
   - ☐ Accredited by the American Association of Tissue Banks
   - ☐ Accredited by FACT
   - ☐ Member of the American Blood Center
   - ☐ Other: ____
   - ☐ Other: ____

2. Describe in detail all processing, quarantine and testing procedures (please attach a separate sheet if necessary):

   ____

   ____

   ____

   ____

3. Is testing performed by a subcontractor? Yes ☐ No ☐
   - i. Do you require a Certificate of Insurance from the subcontractor? Yes ☐ No ☐
   - ii. Are you included as an Additional Insured? Yes ☐ No ☐
   - iii. What are the minimum limits required? ___________________

4. Do you provide testing services for other facilities? Yes ☐ No ☐
   - i. Revenue: ___________________
   - ii. Do you sign a contract with the other facilities? Yes ☐ No ☐

If yes, please attach.

5. Since what date have you continuously tested for the following:
   i. HIV? _____/_____/______
   ii. HTLV-I? _____/_____/______
6. When was your last FDA, regulatory authority or accreditation organization inspection? ______________
   Please attach the report.
7. Do you conduct research activities? Yes ☐ No ☐
   If yes, explain:____
   ____
   ____
8. Do you follow a written quality control program? Yes ☐ No ☐
   i. Do you have a full-time risk manager? Yes ☐ No ☐
   ii. How often do you audit your procedures? ________________
   iii. How often do you perform maintenance of equipment? ________________
9. Do you offer mobile blood units or similar off premises services? Yes ☐ No ☐
   i. Estimated annual number of events: _______________
   ii. Estimated annual number of donors: _______________
   Attach a copy of your contract.

LOSS HISTORY

1. How many adverse events have been reported to you, the FDA and/or any other regulatory authority concerning your clinical trials in the last 5 years? **Please provide details.**
   ____
   ____
   ____
2. Has any license or accreditation ever been suspended or revoked? Yes ☐ No ☐
   If yes, explain: ____
   ____
   ____
3. Has any claim been made against any person or organization proposed for this insurance during the last five (5) years? Yes ☐ No ☐
   If yes, please provide five (5) year loss history for all claims, including any predecessor. Attach a description of any loss greater than $10,000.

Year	No. of Claims	Total Amounts Paid	Amounts Reserved	Total Incurred	Date of Loss Info.

4. Is any person or organization proposed for this insurance aware of any fact, incident, circumstance, situation, condition, defect or suspected defect which may result in a claim, such that would fall under the proposed insurance? Yes ☐ No ☐
   If yes, please provide details. ____
   ____

INSURANCE INFORMATION

1. Has any insurer declined, canceled, or nonrenewed any General Liability, Professional Liability or similar insurance on behalf of any person or organization proposed for this insurance? Yes ☐ No ☐

   If yes, please provide details. ____

2. Provide the following insurance information for the prior five (5) years:

Year	Limits of Liability	Deductible/SIR	Premium	Effective Dates	Retroactive Date

3. Indicate the limits of liability and deductible requested:
   i. General Liability Limits - $__________________/$_________________ Deductible - $__________________
   ii. Professional Liability Limits - $__________________/$_________________ Deductible -$_______________
   iii. Products Liability Limits - $__________________ /$__________________ Deductible - $________________

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: ____