☐ New ☐ Renewal Effective Date: __________

EYE BANK APPLICATION

Some of the coverages being applied for are Claims Made. Claims-Made coverage, subject to the provisions of the policy, applies only to a claim first made during the policy period. No coverage exists for claims made coverage for claims first made after the end of the policy period unless, and to the extent, an extended reporting period applies. If there are questions concerning these coverages, please contact your insurance agent or broker.

Instructions:

1. Please read the instructions carefully. Complete and submit all requested information and/or required attachments. This application and all materials submitted shall be held in confidence.
2. All application questions must be fully answered. If a question does not apply, please write "N/A".
3. If more space is needed, continue on a separate sheet of the applicant's letterhead and indicate the question number.
4. To this application, please attach copies of:
   a. Latest annual financial statement
   b. Claim loss runs for the past 5 or more years for all coverages being applied for, in Excel if available
   c. FDA Form 3356, Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps)
   d. Most recent FDA Inspectional Observations (Form FDA-483)
   e. EBAA Accreditation Certificate & Letter of Corrective Actions (if applicable)
   f. State Inspection Report if required by state law
5. **This application must be completed, signed and dated by a principal of the business.**

I. GENERAL INFORMATION:

Name of Applicant (legal name): ____

Corporate Address: ____

City:______________ State: _____ Zip Code: _____ County: _____

Mailing Address if different: ____

Corporate Contact: ______________________ E-Mail Address: ______________________

Tel. Number: _________________ Fax Number: _________________ Website: ______________

FDA Registration Number/Field Establishment Identifier (FEI): ______________

II. UNDERWRTING GENERAL INFORMATION:

A. Is the applicant EBAA accredited? ☐ Yes ☐ No. If yes, is the accreditation ☐ Comprehensive ☐ Limited

   If Limited, for what services? ☐ Recovery ☐ Processing ☐ Distribution ☐ Other (Describe) _________

B. Have you ever received a Denial of Accreditation? ☐ Yes ☐ No

C. Date of applicant's last EBAA inspection? _____ Date next inspection? _____

D. Named Insured: Provide names and descriptions of all legal entities that are intended for coverage under the policy being applied for. If more space is required, provide by attachment. Please fill in all sections.

Name	Description	% Owned	Date Acquired	Retroactive Date

E. In what states is tissue distributed? List all that apply. ____________________

F. In what states is tissue recovered? List all that apply. ____________________

G. Does the applicant recover tissue outside the United States? ☐ Yes ☐ No

H. Does the applicant distribute tissue outside the United States? ☐ Yes ☐ No

I. How many years has the applicant been in operation? _____ years

J. Within the next 12 month period, does applicant plan to:

1. Obtain another operation or entity? ☐ Yes ☐ No
2. Add to the number of employees? ☐ Yes ☐ No
3. Expand the number of locations? ☐ Yes ☐ No
4. Eliminate/add current services? ☐ Yes ☐ No
5. Operate in other states? ☐ Yes ☐ No

K. Within the past five years has the applicant acquired, sold, or discontinued any operations? ☐ Yes ☐ No

If the response was "Yes" to Questions H or J above, provide details on a separate sheet of paper.

III. SERVICES

A. What services does the applicant or others perform on your behalf? Total must equal 100%.

SERVICE	% PERFORMED BY APPLICANT	% PERFORMED BY OTHERS
Recovery of eye tissue		
Processing eye tissue		
Storage of eye tissue		
Evaluation of eye tissue		
Determination of Donor Eligibility		
Distribution of eye tissue		
Other: (describe)		
Other: (describe)		

Does the applicant operate other than as an Eye Bank? ☐ Yes ☐ No

If yes, explain: ____________________

B. Gross Revenue

	Projected	Current Year	1 Year Prior	2 Years Prior	3 Years Prior
Gross Revenue	$	$	$	$	$

C. Breakdown of Processed Occular Tissue and Revenue by State

STATE	# Processed Occular Tissue by State	% Revenue by State
	#	$
	#	$
	#	$
	#	$
	TOTAL #	**TOTAL**$

D. Provide percentage of donors for the past 12 months. Adult: _____% Pediatric: _____%

E. What is the percentage of donor distribution? Total must equal 100%.

Donor Distribution	Percentage
Tissue for transplant	
Research: describe	
Teaching (i.e. not transplanted into live patients)	
Other: describe	
Total	

F. If infectious disease testing is performed by an outside laboratory is the laboratory:

☐ registered with the FDA ☐ CLIA certified

G. For other functions conducted by external parties, does the applicant require the other establishment to be accredited in their specialty? ☐ Yes ☐ No

If no, please explain. ____________________

H. For all functions performed outside by external parties, does a contract exist between you and the other establishment? ☐ Yes ☐ No

I. What professional liability insurance requirements does the applicant require of the other establishment? $ ______________ each claim $ ______________ aggregate?

IV. ACCREDITATIONS/CERTIFICATIONS/REGISTRATIONS

A. What additional accreditations/certifications are currently held by the applicant? Check all that apply:

☐ American Association of Blood Banks ☐ The Joint Commission (TJC aka JCAHO)

☐ Clinical Laboratory Improvement Act (CLIA) ☐ American Association of Tissue Banks

☐ Other. (List accrediting/certifying organizations.) ____________________

B. Is the Medical Director an ophthalmologist who has completed a corneal fellowship? ☐ Yes ☐ No

C. Does the applicant employ certified eye bank technicians? ☐ Yes ☐ No.

If yes, what percentage of eye bank technicians are certified? _____%

V. COVERAGE REQUESTED

A. Professional Liability:

Current Insurance Carrier:______________ Premium: $______________

Current Form of Insurance:

Check one: ☐ Claims Made ☐ Claims Made - Retroactive Date: ______________ ☐ Occurrence

Limits of Liability: $______________each claim/$______________ aggregate

Do you have a: ☐ Deductible or ☐ Self Insured Retention?

What is Deductible or SIR Amount $ ______________

Do any states in which the applicant operates have a Patient Compensation Fund? ☐ Yes ☐ No

If yes, is the applicant currently enrolled in the Patient Compensation Funds? ☐ Yes ☐ No

B. Commercial General Liability

Current Insurance Carrier: ______________ Premium: $______________

Current Form of Insurance:

Check one: ☐ Occurrence ☐ Claims Made – Retroactive Date: ______________

Limit - Each Claim (cannot exceed PL limit) $ ______________

Limit - Fire Damage Limit of Liability (Any one Fire) $ ______________

Limit - Products-Completed Ops Aggregate Limit $ ______________

Limit - General Aggregate (Other than Products) $ ______________

Do you have a: ☐ Deductible or ☐ Self Insured Retention?

What is Deductible or SIR Amount $ ______________

C. Umbrella Liability *

☐ Has an Umbrella Policy ☐ Does not have Umbrella policy

If Yes, current Insurance Carrier: ______________________

Premium: $ ______________ Limit: $ ______________ Combined Single Limit

Submit Umbrella Accord Application for this coverage. Include Auto and Employee Benefit Liability information if you desire to have this coverage scheduled on your umbrella policy.

D. Employee Benefit Liability: ☐ Do not desire this coverage

Limits of Liability: $ ______________ each claim / $ ______________ aggregate

Total number of Employees _____

Do you want to change your current insurance structure? ☐ ***Yes*** ☐ ***No***

If yes, what limits and or deductible/SIR do you want to consider: Limits: $_________

Deductible: $_________

VI. QUALITY IMPROVEMENT/RISK MANAGEMENT

A. Is a formal Quality Improvement/Risk Management program in place? ☐ Yes ☐ No

B. Is the overall responsibility for Quality Improvement/Risk Management designated to one individual within the administrative structure of the organization? ☐ Yes ☐ No

If yes provide the following information.

Name: ______________ Title: ______________

Telephone Number: (   )   - Email Address: ______________

If no, please describe how these functions are monitored by the Administration.

____

C. Does the applicant have a working relationship with a hospital or university school of medicine for guidance and assistance with medical standard development? ☐ Yes ☐ No

D. If a Limited facility, does the applicant have access to a Medical Director for guidance and assistance with medical standard development? ☐ Yes ☐ No

E. Is written donor's representative consent required in all states regardless of state law? ☐ Yes ☐ No

a. Does the donor's representative consent form specifically list the purposes for which the donated tissue will be used? ☐ Yes ☐ No

b. Are donor's representatives advised in writing of their right to withhold consent for potential uses of donated tissue? ☐ Yes ☐ No

F. Does the applicant provide a copy of signed Consent Form to the donor representative? ☐ Yes ☐ No

G. Does the applicant provide the following to donor families:

a. Bereavement support or access to bereavement services? ☐ Yes ☐ No

b. Eye Bank contact information re. questions regarding the donation? ☐ Yes ☐ No

H. Does the applicant have separate or defined areas for each operation, or other control systems in place to prevent improper labeling, mix-ups, contamination, cross-contamination, and accidental exposure of tissue to communicable disease agents? ☐ Yes ☐ No

I. Are applicant's refrigerators calibrated against the National Institute of Standards and Technology (NIST) standard thermometer at least annually? ☐ Yes ☐ No

J. In the event of a power failure does the applicant have an emergency power supply? ☐ Yes ☐ No

If no, what emergency plans does the applicant have in place? ______________________________

K. Does each occular tissue have a unique identification number to allow tracking and recall? ☐ Yes ☐ No

L. Is all tissue individually packaged and sealed with tamper-evident seals? ☐ Yes ☐ No

M. Have you had any adverse events, recalls, warnings and/or withdrawals related to donation in the past five years? ☐ Yes ☐ No

If yes, describe in detail the event and corrective action plan initiated or implemented. ______________

____

N. Clinical Records:

1. Are records stored: ☐ electronically or ☐ paper files or ☐ both?

a. If electronic, how often are records backed up? ______________

b. If paper, where are records stored? ☐ on site ☐ offsite?

c. Are the buildings in which paper records stored sprinkled? ☐ Yes ☐ No

VII. EMPLOYEES/INDEPENDENT CONTRACTORS INFORMATION

A. Employees/Independent Contractors

Staff	Number Full-Time	Number Part-Time	Annual Payroll	Number of 1099's
Call Center Staff				
Certified Eye Bank Technician				
Compliance Officer				
Donor Information Officer				
Donor Screening Specialist				
Lab Technician				
Medical Director/Assoc. Med. Dir./Backup Med. Dir.				
Nurses (RN, LPN, LVN)				
Physician Assistant				
Physicians				
Processing Technologist				
Public Relations Coordinator				
Quality Director				
Referral Coordinator				
Students				
Tissue Recovery Specialist/Technician				
Tissue Services Director				
Triage Coordinator				
Volunteers				
Other (Specify)				

B. Percentage of turnover

1. Staff licensed/certified by the state __________ %
2. Non-licensed/certified staff __________ %

C. Hiring/Screening and Employment Procedures

1. Are employees/contractors references contacted before hiring or placement? ☐ Yes ☐ No
2. How are references checked? ☐ Written ☐ Verbal ☐ Both
3. Does applicant verify pending license suspensions, revocations, or pending disciplinary actions by other facilities? ☐ Yes ☐ No

VIII. GENERAL LIABILITY

A. Does applicant sponsor any sporting or special events? ☐ Yes ☐ No

If Yes, please explain? ____

If, Yes, does the applicant provide alcoholic beverages at any of these events? ☐ Yes ☐ No

If Yes, please explain? ____

B. Is all advertising, public relations, media, website content reviewed by legal counsel or risk management? ☐ Yes ☐ No

IX. LITIGATION/CLAIMS HISTORY/SANCTIONS/FINES

If the response is yes to any question below additional information must be provided on the applicant's letterhead.

A. Has the applicant had any Professional Liability, General Liability, Employee Benefits or Umbrella claims or suits brought against them in the past 5 years? ☐ Yes ☐ No

B. Is the applicant aware of any incident (including requests for medical records), circumstance or occurrence which may result in a claim and which has not been reported to another carrier? ☐ Yes ☐ No

C. Has the facility/operational state license ever been suspended, revoked or voluntarily suspended? ☐ Yes ☐ No

D. Has any Insurance Company or Lloyd's syndicate declined, canceled, or refused to renew or accept any of the applicant's liability insurance? ☐ Yes ☐ No

E. Has any Company with whom the applicant been previously affiliated with become insolvent? ☐ Yes ☐ No

F. Has any federal or state civil or criminal investigation or action been initiated or filed that directly or indirectly involve the applicant's organization? ☐ Yes ☐ No

G. Has the applicant ever been sanctioned or decertified by Medicare? ☐ Yes ☐ No

H. Has the organization or any of its officers, administrators, or staff been sanctioned or had disciplinary actions brought against them by federal or state authorities, any professional medical society, accreditation agency or other governmental or non-governmental oversight entity? ☐ Yes ☐ No

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AUTHORIZATION

I have answered the questions in the Application to the best of my ability and declare that, to the best of my knowledge, the statements set forth herein are true and correct. My signing of the Application does not bind the Insurance Company to complete the insurance, but it is agreed that this Application shall be the basis of the contract should a policy be issued.

FRAUD NOTICE – Where Applicable Under The Law of Your State

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 or incomplete information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime and may be subject to civil fines and criminal penalties (for New York residents only: and shall also be subject to a civil penalty not to exceed five thousand dollars and the stated value of the claim for each such violation.) (For Pennsylvania Residents only: Any person who knowingly and with intent to injure or defraud any insurer files an application or claim containing any false, incomplete or misleading information shall, upon conviction, be subject to imprisonment for up to seven years and payment of a fine of up to $15,000.) (For Tennessee Residents only: Penalties include imprisonment, fines and denial of insurance benefits.)

Signature in full　　　　　　　　　　　　Date

Name - please print

ALL QUESTIONS MUST BE ANSWERED AND THE APPLICATION MUST BE SIGNED AND DATED.

Agency Name and Address	Person Submitting Application	Telephone Number	E-Mail Address

This product will be underwritten in one of the CNA property/casualty companies. CNA is a registered service mark and trade name of CNA Financial Corporation.