PRE-INSPECTION QUESTIONNAIRE INSTRUCTIONS

- Submit copies of all documents or records outlined below. If you do not have the required information, indicate whether or not you expect to have it at the time of the site inspection. This information will be included in the final score by which your accreditation status is determined.

- Fill in all blanks on pre-questionnaire charts. If you are unable to answer any questions, indicate you will have the information available at the time of inspection **or give reason(s) you consider the information requested to be not applicable to your eye bank's operations.**

- The information submitted in this Pre-Inspection Questionnaire shall reflect all agencies, services, certifications, etc. utilized **since the date of your eye bank's last EBAA inspection**.

- If you do not understand the questions, please contact your Lead Inspector or the Chair(s) of the Accreditation Board.

QUESTIONNAIRE

1. Please provide the following information for all agencies with which the eye bank contracts services or if the eye bank performs the activities itself, e.g., infectious disease testing, sterilization, microbiology, etc. **Documentation provided for accreditation / certification (CLIA/FDA/EBAA) must cover each year the agency was used by the eye bank since the date of the eye bank's last inspection.**

D1.200	**1-A. INFECTIOUS DISEASE TESTING:** Please provide the requested information in the attached chart labeled WORKSHEET #1-A.
C3.300, C3.510, C3.700	**1-B. ALL OTHER SERVICES:** Please provide the requested information in the attached chart labeled WORKSHEET #1-B. *(EBAA Accredited Eye Banks that you contract with to perform eye banking functions should be included in this section.)*
C1.300, C2.000	**1-C. RECOVERY, PRESERVATION, AND/OR PROCESSING SERVICES BY NON-EMPLOYEES:** Please provide the requested information in the attached chart labeled QUESTION #1-C. *(Examples of non-employees are individuals directly contracted with by the eye bank, or employees of a non-EBAA Accredited facility that perform recovery, preservation or processing functions for your eye bank.)*

2. Please provide the following:

C1.100-C1.300	**2-A. STAFF:** Please provide the requested information for **all** individuals who have performed the identified functions **since the date of the eye bank's last inspection** in the attached chart labeled WORKSHEET 2-A. Also, please provide your current organizational chart.
C1.300	**2-B.** For all authorized staff performing eye bank functions, provide written statement from the Medical Director or designee specifying which procedures each individual is qualified to perform independently, including suitability and release of tissue for transplant.
C2.000	**2-C.** Provide documentation that the person (or persons) conducting annual competency reviews is a CEBT or is an individual who has been qualified by a CEBT who is part of the organization's quality program.
C1.200	**2-D.** Provide documentation that the Staff Trainer has been observed annually by the Medical Director.

3. Please provide the following information:

C1.200	**3-A.** Name of Medical Director
C1.200	**3-B.** Provide documentation of Medical Director qualifications (corneal fellowship, demonstration of expertise in corneal surgery, OR documentation of a consulting relationship with an ophthalmologist who has completed a corneal fellowship).
C1.200	**3-C.** Name and qualifications of back-up Medical Director.
C1.300	**3-D.** If the Medical Director fulfills the role of CEBT in a supervisory position, provide documentation of current certification.
C3.500	**3-E.** If the facility performs specialized or specific eye banking functions, provide documentation that it has a Medical Director or has access to a Medical Director through a documented consultative relationship with an accredited organization.

4. Please submit the following documentation:

C1.200	**4-A.** A copy of the Medical Director's certificate of attendance at the Medical Directors' Symposium of an EBAA Annual Meeting at least once every three (3) years and a Medical Advisory Board meeting once every three years in the time period preceding this scheduled site inspection.
C1.300	**4-B.** Copy/copies of the certification/recertification of the eye bank's CEBT in a supervisory role covering the three (3) years preceding this scheduled site inspection.

B1.000	**4-C.** A copy of the eye bank's annual FDA registration for each year since the last inspection.
C3.200	**4-D.** A copy of annual certification for Processing Environment(s), as well as certification following any move of a Laminar Flow Hood, for each year since the last inspection.
C3.200	**4-E.** Provide documentation that the continuous temperature recorder has been calibrated at least annually against a NIST thermometer, for each year since the last inspection.
C3.200	**4-F.** Provide documentation of the annual calibration of cell counting equipment for each year since the last inspection.
J1.000	**4-G.** A sample of a completed label used for each type of tissue distributed by the eye bank (e.g., corneoscleral disc, sclera or whole eye for surgery and/or research or training use).
B1.000	**4-H**. Documentation that registration with ICCBBA for FIN has been maintained for each year since the last inspection.

5. Describe, in one page or less:

J1.000	**5.** The system used by your eye bank to assign donor and tissue numbers (i.e., identification system). Include how unique ISBT Tissue Identifiers are used to identify each surgical tissue or fraction thereof. Provide sufficient detail that inspectors can make a preliminary determination of records to be selected for review during the site visit. Include any samples that you think would help the inspectors to understand your system.

6. Using the following donor profile,

D1.200	**6.** Complete your eye bank's plasma dilution worksheet or explain how you would apply your eye bank's plasma dilution algorithm to determine whether or not a pre-transfused specimen is required. Indicate what (if any) additional information you would seek in order to make the determination.

DONOR PROFILE:

Upon reviewing all medical records available, you find the following information:

> EMS was called to a residence for a 75 y/o individual (weighing 60 Kg.) c/o chest pain. Upon arrival at 1055, patient was found to be in CPA. ACLS was started, along with an IO line (250 cc bag of Normal Saline) established to the right lower leg at 1057 infusing at wide-open rate. After approximately 3 minutes of CPR, a weak heartbeat was regained. The patient was transported to a local ER. Upon arrival to the ER, at 1120, a peripheral line was established with a liter bag of Lactated Ringers infusing at wide-open rate. No blood sample was drawn in the ER upon arrival, or by EMS prior to arrival.

After emergent evaluation, the patient was taken to the cath lab at 1137, where a 2nd peripheral line was established, at 1140, with a liter bag of Lactated Ringers infusing at 200 cc per hour. At 1139, the peripheral IV started in the ER upon arrival infiltrated and access was lost.

The cath lab procedure started at 1150. At approximately 1205, one of the cardiac vessels was ruptured and 2 units of PRBC were ordered to be given with a rapid infuser. The 2 units of PRBC, via rapid infuser, were begun at 1208. The OR was alerted that the patient was being brought to the OR for an emergent bypass. At 1210, the patient went into CPA and ACLS was begun. The patient arrived in the OR suite at 1213, with ACLS in progress. During the surgical prep of the patient, the surgeon decided to end resuscitation and the patient was pronounced dead at 1218.

Calculate fluid status using your eye bank's plasma dilution worksheet /algorithm and specify whether the post-mortem sample is sufficient for infectious disease testing. A copy of the worksheet or the calculations performed to determine fluid status must be included.

M1.300-M1.500	**7-A.** Please attach a copy of **each form used by the eye bank to record donor and recipient information**. Be sure to include any forms that are filed in your donor/recipient records, such as screening forms, checklists, body inspection forms, autopsy forms, slit lamp and specular microscopy forms and recipient follow-up forms, as well as labels requested in Question 4-G.
L1.100	**7-B.** Please attach a copy of your Tissue Report Form.
L1.200	**7-C.** Please attach a copy of your Package Insert.
B1.200	**8.** Please provide confirmation that if the eye bank was inspected by an official agency and received any written documentation of observations, findings or results (including, but not limited to, FDA Form 483) that a copy was sent to the EBAA Office within ten (10) business days of receipt.
	9. Send a copy of your Policy & Procedure Manual, the completed questionnaire, accompanying documentation, and Declaration of Compliance with Governmental Regulations to both inspectors assigned to your bank. In order to facilitate review of the Policy & Procedure Manual, your bank must either tab your SOPs to correspond with each question in Section 2 of the Site Inspection Questionnaire or provide a separate document (crosswalk) that clearly explains where the inspectors can locate information pertaining to each question in Section 2 of the Site Inspection Questionnaire. ***Your inspectors must receive <u>all</u> materials no later than twenty (20) working days before the scheduled date of your inspection.***

Please have all individuals who assisted in the completion of the questionnaire sign in the spaces provided below. In addition, the Director should sign in the designated space to verify his/her approval and the accuracy of the contents.

_____	_____
_____	_____
_____	_____
_____	_____
Director	Date

NOTE: THIS COMPLETED QUESTIONNAIRE, ACCOMPANYING DOCUMENTATION, DECLARATION OF COMPLIANCE WITH GOVERNMENTAL REGULATIONS AND YOUR POLICY & PROCEDURE MANUAL SHOULD BE SENT DIRECTLY TO YOUR TWO ASSIGNED SITE INSPECTORS FOR ARRIVAL NO LATER THAN TWENTY (20) WORKING DAYS PRIOR TO THE SCHEDULED DATE OF INSPECTION.

PRE-INSPECTION QUESTIONNAIRE WORKSHEET

QUESTION #1-A: **INFECTIOUS DISEASE TESTING (Please provide this information whether testing is done by the eye bank or by an outside lab.)**
Provide Copies of Documentation of <u>each year</u> of Accred., Certif. (CLIA/FDA), etc. for each lab since last inspection.

NAME OF INFECTIOUS DISEASE TESTING LAB	DATES LAB PROVIDED SERVICES	ACCRED. AND/OR REG. AGENCIES	TESTS PERFORMED	METHODOLOGIES USED	VALIDATION OR CONTROL PROCEDURES/FREQUENCY

PRE-INSPECTION QUESTIONNAIRE WORKSHEET

QUESTION #1-B:	**ALL OTHER SERVICES (Please provide information for all agencies, including the eye bank, which provide services; i.e., instrument sterilization, biohazardous waste disposal according to state and federal regulations; eye banking functions provided by another eye bank or entity)** **Provide Copies of Documentation of <u>each year</u> of Accred., Certif. (CLIA/FDA), etc. for each agency since last inspection.**			
NAME OF AGENCY	DATES AGENCY PROVIDED SERVICES	TYPE OF SERVICE	ACCREDITING AND/ OR REGULATORY AGENCIES	VALIDATION OR CONTROL PROCEDURES AND FREQUENCY (if applicable)

PRE-INSPECTION QUESTIONNAIRE WORKSHEET

QUESTION #1-C:	**RECOVERY, PRESERVATION, AND/OR PROCESSING SERVICES BY NON-EMPLOYEES (Please complete the requested information below AND submit documentation to confirm the training, certification, and annual review of any <u>non-employees</u> that recover or process ocular tissue on behalf of your eye bank for each year since your last inspection. Also include any applicable licensure or accreditation documentation of the non-employee's employer for each year since last inspection.)**			
NAME OF NON-EMPLOYEE	EMPLOYEE PROVIDED SERVICES	TYPE OF SERVICE(S) PROVIDED	NON-EMPLOYEE'S EMPLOYER	ACCREDITING AND/OR REGULATORY AGENCIES

PRE-INSPECTION QUESTIONNAIRE WORKSHEET

QUESTION #2-A: STAFF Please list the names of all staff authorized by the eye bank to perform identified functions for each year since your last inspection and indicate employment status (e.g., full time, part time, on call).

NAME	EMPLOYMENT STATUS	DATES OF EMPLOYMENT	CEBT Y/N	INITIAL DONOR SCREENING	RECOVERY/PROCESSING						TISSUE EVALUATION		DETERMINE FINAL TISSUE SUITABILITY	DETERMINE FINAL DONOR ELIGIBILITY
					IN SITU EXCISION	ENUCLE-ATION	C-S DISC IN LAB	EK PROC	DMEK PROC	OTHER PROC	SLIT LAMP EYE/CORNEA	SPECULAR		

PRE-INSPECTION QUESTIONNAIRE WORKSHEET

QUESTION #2-A: STAFF Please list the names of all staff authorized by the eye bank to perform identified functions for each year since your last inspection and indicate employment status (e.g., full time, part time, on call).

NAME	EMPLOYMENT STATUS	DATES OF EMPLOYMENT	CEBT Y/N	INITIAL DONOR SCREENING	RECOVERY/PROCESSING						TISSUE EVALUATION		DETERMINE FINAL TISSUE SUITABILITY	DETERMINE FINAL DONOR ELIGIBILITY
					IN SITU EXCISION	ENUCLE-ATION	C-S DISC IN LAB	EK PROC	DMEK PROC	OTHER PROC	SLIT LAMP EYE/CORNEA	SPECULAR		