

APPLICATION FOR SITE INSPECTION
Eye Bank Association of America

Complete this application to begin the process for inspection and accreditation by the Eye Bank Association of America (EBAA). See the EBAA's Accreditation Policies and Procedures, Medical Standards, and Constitution and Bylaws for more information about EBAA inspections and accreditation policies and procedures.

This application should be completed for any establishment that performs any Eye Bank Function (as outlined in Section II) and is seeking EBAA accreditation (e.g. comprehensive and limited function eye banks).

If the eye bank / entity completing this application performs any Eye Bank Function at more than one location and/or contracts with other organizations for eye banking services, some sections of this application may need to be copied in order to complete the application (as indicated).

An application will not be considered complete and inspector(s) will not be assigned until all information is provided to the satisfaction of the EBAA Accreditation Board Chair(s). Additional documentation may be required upon review of your application. If you have questions about this application or the required supporting documentation, please contact Jennifer DeMatteo at 202-775-4999, ext.117 or via email at jennifer@restoresight.org.

I. CONTACT INFORMATION

1. Name of Eye Bank Applying for Inspection _____

Address _____

City _____ State _____ Zip Code _____

Phone # _____ Fax # _____

2. Parent Organization Name (if applicable) _____

Address _____

City _____ State _____ Zip Code _____

3. Name of Person Completing Application _____ Date _____

Title _____ Address _____

Email _____ Phone # _____

4. Medical Director Name _____

Is the Medical Director an ophthalmologist (EBAA MS C1.200)? Yes No

Has the Medical Director completed a corneal fellowship? Yes No

If Yes, Fellowship location _____ Year completed _____

If No, do you have documentation of a consulting relationship with an ophthalmologist who has completed a corneal fellowship? Yes No

Consulting Ophthalmologist's Name _____

Fellowship location _____ Year completed _____

Does the Medical Director fulfill the role of an EBAA CEBT in a supervisory and training position? Yes No

If yes, year of initial CEBT certification _____ Year of last re-certification _____

5. Back-up Medical Director Name _____

Is the Back-up Medical Director an ophthalmologist (EBAA MS C1.200)? Yes No

Has the Back-up Medical Director completed a corneal fellowship? Yes No

If Yes, Fellowship location _____ Year completed _____

6. Does your bank employ at least one EBAA Certified Eye Bank Technician (MS C1.300)? Yes No

If Yes, provide: CEBT Name _____

Year of initial CEBT certification _____ Year of last re-certification _____

If No, provide: Consulting CEBT Name _____

Organization Name _____

Is this organization EBAA Accredited? Yes No

7. Executive Director / CEO Name _____

Email _____ Phone # _____

Is the Executive Director / CEO also a CEBT? Yes No

If yes, year of initial CEBT certification _____ Year of last re-certification _____

8. Are cleaning and maintenance records, equipment certifications, and monitoring charts available for review at the main location applying for site inspection? Yes No

9. Does your bank have donor records readily available for review including recipient follow-up information and adverse reaction files since your last EBAA inspection or within the past three years (whichever is less)? Yes No

10. Complete the Proficiency Verification Form (see page 4). Verify your bank / entity handled at least 25 surgical corneas within the past 12 months for each Eye Bank Function (as defined by EBAA) your bank / entity is applying to become accredited for at this time. Yes No

11. Does the eye bank have sufficient whole eyes / corneoscleral discs to demonstrate practical recovery or processing techniques as outlined in the Accreditation Policy & Procedures Yes No*
**If No, the Applying Eye Bank must make arrangements to acquire adequate tissue for the day of inspection.*

12. Does the eye bank have a Policy and Procedures Manual ready for submission and review by the Accreditation Board? Yes No

13. Have you had a Change in Governance since your last EBAA inspection or within the past three years (whichever is less) including a change in the type(s) of Eye Bank Functions this bank performs? Yes No

If yes, please describe: _____

If yes, was the Change in Governance reported to the EBAA Office and the Chair(s) of the Accreditation Board as required by EBAA MS C1.400? Yes No

14. Has your facility been inspected by the FDA since your last EBAA inspection or within the past three years (whichever is less)? Yes No

If yes, date of inspection: _____

Was a 483 or any other citation issued? Yes No

If yes, please describe: _____

Did your bank forward all written documentation of observations, findings or results to the EBAA Office and the Chair(s) of the Accreditation Board as required by EBAA MS B1.200? Yes No

Please attach copies of 483s and/or any other citations / documentation that the bank or FDA issued.

15. Has your facility been inspected by any other Official Agencies since your last EBAA inspection or within the past three years (whichever is less)? Yes No

If yes, please provide the name(s) of the Agenc(ies) that inspected your facility and the dates of any inspection(s). Provide the scope of the inspection and it's findings to this application. This information will be reviewed by the Accreditation Board Co-Chair(s).

Did your bank forward all written documentation of observations, findings or results to the EBAA Office and the Chair(s) of the Accreditation Board as required by EBAA MS B1.200? Yes No

16. Complete the remainder of this application.

This application must be returned by the deadline date indicated on the accompanying memo. **Note: *Delay of your site inspection will affect your accreditation status.*** It is your responsibility to respond promptly! Please retain one copy for your file and return a copy to the EBAA office:

**Eye Bank Association of America
1101 17th Street, N.W., Suite 400
Washington, DC 20036
(202) 775-4999, Extension 117
Fax: (202) 429-6036**

FILING FEES:	APPLYING BANK / ENTITY	\$500
	EACH PHYSICALLY INSPECTED SATELLITE	\$250

EYE BANK / ENTITY PROFICIENCY VERIFICATION – Must be completed for all applications.

Complete the form below to verify the handling of at least 25 surgical corneas annually for each Eye Bank Function (as defined by EBAA) the eye bank / entity is applying to become accredited for (MS B1.000). Identify at least 25 surgical tissue ID numbers *from within the past 12 months*, and document every Eye Bank Function that applies to that tissue ID for which the eye bank / entity is applying for accreditation. (Multiple functions may be marked for any particular tissue ID.)

	Tissue ID#	Recovery	Processing	Tissue Storage	Tissue Evaluation	Donor Eligibility Determination	Final Distribution
1							
2							
3							
4							
5							
6							
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8							
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31							
32							
33							
34							
35							
	TOTALS						

(May continue on another form if necessary.)

II. GOVERNANCE / FUNCTIONS

The EBAA accredits banks for the following eye bank functions. After completing this application, the EBAA Accreditation Co-Chairs will review the information to determine the scope of the inspection required. Please make sure to complete all questions completely.

Recovery: The establishment procures ocular tissues, which may encompass, but is not limited to: in situ excision, whole eye enucleation, donor body assessment, pen light examination, assignment of a unique ISBT 128 Tissue Identifier, storage solution storage, pre-distribution packaging of tissue, supply storage, sterilization of instruments. (EBAA Medical Standards: the removal, acquisition, recovery or collection of donor tissue)

Processing: Post-recovery, the establishment prepares ocular tissues, which may encompass, but is not limited to: processing (e.g. laboratory corneoscleral disc excisions, laboratory scleral preservation, preparation of lamellar tissue, preparation of tissue for LAK), supply storage, sterilization of instruments, environmental control/cleaning, storage solution storage and pre-distribution packaging of tissue. (EBAA Medical Standards: Any activity performed on the eye tissue, other than recovery, donor screening, donor testing, storage, labeling, packaging, or distribution, such as: testing for microorganisms; preparation, sterilization, steps to inactivate or remove adventitious agents; preservation for storage; manipulation/sizing and removal from storage. Any manipulation of the ocular tissue intended for transplant that involves opening a previously sealed container after recovery.)

Tissue Storage: The establishment stores transplantable ocular tissue, which may encompass, but is not limited to: Refrigerator control (temperature monitoring), quarantine requirements, and others, as appropriate to the scope of the inspection. (EBAA Medical Standards: The maintenance of ocular tissue for future use.)

Final Distribution: The facility releases the tissue for distribution to the end user, which may encompass, but is not limited to: handling of recipient records, packaging tissue for distribution, labeling tissue, seeking post-operative follow-up reports, tracking of the tissue, assignment of a unique ISBT 128 Tissue Identifier. (EBAA Medical Standards: A process of allocation of tissue for transplant, research or educational use. This process includes receipt of request, selection, inspection and release of tissue, to a consignee such as a surgeon, surgical center or educational research center. The principles of tracking, traceability and adverse reaction reporting will be maintained throughout the process of distribution.)

Tissue Evaluation: The establishment performs slit lamp microscopy and/or specular microscopy of ocular tissue, which may encompass, but is not limited to: determination of endothelial density, equipment calibration and maintenance. (EBAA Medical Standards: The performing of any and/or all of the following on eye tissue intended for transplant: slit lamp examination, endothelial cell density, and pachymetry measurement.)

Donor Eligibility Determination: The establishment makes the final determination of donor suitability, which may encompass, but is not limited to: signing off on donor screening and testing, including the review of donor physical assessment, medical/ social history, plasma dilution, infectious disease testing results. (EBAA Medical Standards: The evaluation of all available information about a potential donor to assess whether the donor meets qualifications specified in the SOP and standards. This includes, but is not limited to: medical, social, and sexual histories; laboratory test results; physical assessment or physical examination; and autopsy findings (if performed).)

For additional information, see EBAA Medical Standards and Accreditation Board Policies and Procedures.

Below, document any and all of the eye banking tasks performed by the applying eye bank / entity, any physically separate satellite (or other) locations, or any contracted establishments. Once completed, this application is evaluated by the EBAA Accreditation Board Co-Chairs. If a site inspector finds conflicting information when conducting the inspection, it may lengthen or prematurely terminate the inspection, so please fill this section out accurately.

If you have any questions about these functions, please contact the Accreditation Board Co-Chairs via email or telephone.

III. EYE BANK FUNCTION OR TASK) IDENTIFICATION – FOR APPLYING EYE BANK / ENTITY– Must be completed for all applications.

Tasks		Entities that Perform the Task		
		Applying Eye Bank / Entity	Physically Separate Satellite (or Other) Location(s) List name(s) of Location, city and state	Contracted Establishment(s) Provide name(s) of each entity
1	Perform body examination or physical assessment	Yes No		
2	Perform a pen light examination	Yes No		
3	Perform ocular recoveries (ie. enucleation / in-situ)	Yes No		
4	Perform laboratory corneoscleral disc excisions	Yes No		
5	Preserve sclera	Yes No		
6	Perform microkeratome processing for EK	Yes No		
7	Perform processing for DMEK	Yes No		
8	Perform laser (e.g. femtosecond) assisted processing	Yes No		
9	Perform tissue transfers, scleral trims or blood rinsing	Yes No		
10	Perform Processing other than those listed above in #4-9 (see MS Glossary for definition of Processing) Describe:	Yes No		
11	Perform the plasma dilution calculations	Yes No		
12	Obtain answers to the medical/social history questionnaire	Yes No		
13	Perform slit lamp examination	Yes No		
13	Evaluate tissue using a specular microscope	Yes No		
15	Determine donor eligibility	Yes No		

III. EYE BANK FUNCTION OR TASK IDENTIFICATION – FOR APPLYING EYE BANK / ENTITY (Continued)

	Tasks	Entities that Perform the Task		
		Applying Eye Bank / Entity	Physically Separate Satellite (or Other) Location(s) List name(s) of Location, city and state	Contracted Establishment(s) Provide name(s) of each entity
16	Evaluate infectious disease testing results	Yes No		
17	Store storage solution(s)	Yes No		
18	Store ocular tissue	Yes No		
19	Maintain refrigerator records on-site	Yes No		
20	Maintain cleaning and environmental monitoring records on-site	Yes No		
21	Maintain tissue evaluation records on-site	Yes No		
22	Store instruments	Yes No		
23	Maintain donor files on-site	Yes No		
24	Perform instrument sterilization in-house	Yes No		
25	Label tissue for distribution	Yes No		
26	Provide a unique ISBT 128 Tissue Identifier for each tissue	Yes No		
27	Track tissue	Yes No		
28	Ship tissue released for transplant to surgeons	Yes No		
29	Maintain complete donor or recipient case records on site	Yes No		
30	Seek rec't follow-up information 3-6 months post-op	Yes No		

IV. SATELLITE (OTHER) LOCATIONS / CONTRACTED ESTABLISHMENTS – Must be completed on all applications.

If a Satellite (or Other) Location or a Contracted Establishment was listed as performing a Task outlined in Section III above, complete the chart below for each, marking “yes” or “no” as appropriate. *(The Eye Bank applying should not be included as it is addressed elsewhere in this application.)*

Organization Name	Medical Director? (Does the entity have one)	CEBT on staff?	EBAA Accredited?	FDA Registered?	CLIA certified?	Joint Commission Accredited?	State Inspected?	Comments

V. SATELLITE (OR OTHER) LOCATIONS – Must be completed for all applications.

1. Is the applying Eye Bank / Entity (the facility applying for site inspection), a subsidiary or part of another organization? Yes No

For example, if this bank is a Satellite, “yes” should be checked.

If Yes, Name of the Organization (bank is a subsidiary of) _____

Executive Director / CEO Name _____

Medical Director Name _____

2. Does the applying Eye Bank / Entity (the facility applying for site inspection), own, operate or use any *physically separate location(s)* Yes No

for the performance of any eye bank tasks or functions (not including Contracted Establishments)?

List All Physically Separate Locations

Location: Name, City and State	Is this location separately registered with FDA?	Has this location already been included for inspection during a different EBAA Accreditation Cycle?
	Yes No	Yes No
	Yes No	Yes No
	Yes No	Yes No
	Yes No	Yes No
	Yes No	Yes No
	Yes No	Yes No
	Yes No	Yes No

For each physically separate location, complete the following information. Make as many copies as necessary of this page to complete for all physically separate locations.

Name of Location _____ Phone # _____

Address _____

Name of Lead Staff at this Location _____ Title _____ Email _____

Does the location have it's own Policy and Procedures Manual? Yes No
If No, what Policy and Procedures Manual does the facility use (Name of Organization)? _____

Does the location have a CEBT on staff? Yes No

If Yes, provide: CEBT Name _____
Year of initial CEBT certification _____ Year of last re-certification _____

If No, provide: Consulting CEBT Name _____
Organization Name _____
Is this organization EBAA Accredited? Yes No

Does the location have or have access to a qualified Medical Director or his/her designee? Yes No
Is the Medical Director an Ophthalmologist? Yes No

Medical Director Name _____ Phone # _____

Address _____

Email _____ Fax _____

How many surgical corneas did this location handle over the past year (January 1 to December 31)? _____

This includes any of the following: recovered, processed, stored, evaluated, determined donor eligibility, or distributed the ocular tissue.

Check the box for each eye banking function performed at this location: Recovery Processing Tissue Storage
 Tissue Evaluation Donor Eligibility Determination Final Distribution

VI. NOTES TO ACCREDITATION CO-CHAIR(S)

Please use this section to provide any additional information you deem important for the accreditation board co-chairs to have regarding your inspection.