Medical Advisory Board Meeting Minutes
Loews Kansas City – June 7, 2024

Dr. Winston Chamberlain called the meeting to order. The following Board members were in attendance:

Winston Chamberlain, MD, PhD	MAB Chair
Shahzad Mian, MD	MAB Vice Chair
Alan Blake, CEBT, CTBS	
Lisa Brooks, CEBT, CTBS	Accreditation Board Co-Chair
Jason Brosious, RN, CEBT, CTBS	
Scott Brubaker	FDA Liaison, Ex-Officio
Kevin Corcoran, CAE	EBAA President & CEO
Maria Cortina, MD	
Andrea Crosson, CEBT	
Jennifer DeMatteo, MCM, CIC	EBAA Director of Regulations & Standards
Marcy Dimond, CEBT, CTBS	
Donna Drury, CEBT, CTBS	
Mark Greiner, MD	
Chris Ketcherside, MD	
Jennifer Li, MD	EBAA Chair
Amy Lin, MD	
John Lohmeier, CEBT	
Kristin Mathes, MS, MA	
Kristen McCoy, CEBT, CTBS	
Eric Meinecke, CEBT	Medical Advisory Board Secretary
Brian Philippy, CEBT	
Edwin Roberts, CEBT	
Roni Shtein, MD	
Adam Stockman, CEBT	
Chris Stoeger, CEBT, CTBS	
Michael Tramber, CEBT, CTBS	
Concetta Triglia, CEBT	
Elmer Tu, MD	Medical Review Subcommittee Chair
David Verdier, MD	

A motion was made and seconded to approve the minutes from the November 2, 2023 Medical Advisory Board meeting held in San Francisco, CA. **The minutes were approved.**

Dr. Elmer Tu presented the Medical Review Subcommittee Report. The number of adverse events per 10,000 grafts has remained relatively steady over the last several years. Dr. Tu spoke briefly about graft failures for donor tissues preserved with antifungal supplementation. While antifungal supplementation is much more common, there still are some banks that do not offer it. While processed tissues are much more likely to have antifungal added to the storage solution, there are some surgeons requesting it for all grafts, including corneas used in PK procedures. Other interventions to decrease infections, such as the requirement for 5% povidone-iodine solution to come in contact with the donor tissue twice during preservation, make it difficult to determine if antifungal supplementation has had much of an impact.

Dr. Win Chamberlain presented the Policy and Position Review Subcommittee (PPRS) Report as Dr. Asim Farroq was unable to attend the meeting. Dr. Chamberlain expressed his appreciation for Dr. Farroq and the PPRS, which has been very busy. Dr. Chamberlain quickly reviewed the PPRS's updates on COVID-19 and Mpox and shared that the subcommittee is currently working on guidance related to Chagas.

Lisa Brooks presented the Accreditation Board Report. 18 banks were inspected during the spring 2024 cycle. All 18 received a 3-year accreditation.

Adam Stockman presented the Certification Board Report. The Certification Board met in January and created a process for individuals with a disability who are eligible to take the CEBT Exam to receive reasonable accommodation if necessary to be able to apply to take the exam. EBAA will accommodate qualified candidates with a disability who are unable to perform the Practical Performance Competency Verification. To request a reasonable accommodation, submit a formal letter to the EBAA Certification Board signed by the eye bank's Executive Director and Medical Director with the request for accommodation, the reason for the accommodation, and a proposed alternative for the demonstration of knowledge equivalent to the practical demonstration. The request should be sent to Stacey Gardner, EBAA Director of Education. The Certification Board will review the requests and contact the individual once the request has been reviewed and a decision has been made. This verbiage has been added on the exam website.

EBAA has posted a roster of current Certified Eye Bank Technicians (CEBTs) on the member section of the EBAA website. To view a list of current CEBTs, log into the members section of the website, and select CEBT Roster from the resources tab.

The Spring 2024 Certified Eye Bank Technician Exam took place April 6 - 20, 2024, in the US, Canada, Greece, and Saudi Arabia. A total of 27 candidates took the exam and 18 individuals passed the exam, resulting in a 67% passing rate. Congratulations to everyone who passed the exam and a special recognition to Jacquelyn Romero from Rocky Mountain Lions Eye Bank for receiving the highest score of the exam cycle.

EBAA is working with the Professional Testing Corporation and members of the Exam Committee to update the current exam item bank using questions recently created and submitted by the Exam Committee and will be reviewing and updating the exam before the Fall Exam cycle. The Fall 2024 CEBT Exam takes place October 12-26, 2024, and the application is now available on the EBAA website.

Individuals who are up for recertification in 2024, can apply for recertification now through December 2024.

Stacey Gardner presented the Technician Education Committee Report. The Technician Education Committee has been productive this year. Stacey thanked the committee for their hard work and their many contributions to the technical education of the EBAA membership.

The Technician Education Seminar (TES) was held virtually in January and February. There were 44 attendees from the US, Puerto Rico, Canada, Germany, and Ukraine. The course featured 28 on-demand presentations and 3 live workshops. New speakers, topics, presentations, and other components have been added to the TES.

In January, Tech Ed hosted the webinar, *Fuchs Endothelial Corneal Dystrophy: Overview, Current Treatment, and Future Therapies* with Dr. Ula Jurkunas from Mass Eye and Ear/ Schepens Eye Research Institute. May's webinar, DSAEK Corneal Tissue Preparation Basics, was presented by Chelsea Green from Iowa Lions Eye Bank, Nicholas Hicks from Eversight, and Paul Graves from Advancing Sight Network.

EBAA is teaming up with AATB for an upcoming webinar in December on recovering tissue and eye banks and tissue recovery agencies working together on shared cases.

The Technician Education Committee continues to create resources for the membership, including training videos for eyeLEARN.

The committee has been planning many of the sessions that have been presented at the 2024 Annual Meeting, including several sessions with live demos or interactive components. The committee planned the Technical Skills Workshop as well as the following sessions:

- DMEK 2.0: Beyond the Basics
- Navigating the Technical Staffing Merry-Go-Round
- Ocular Tissue Recovery – Wet Lab, Demos, and Discussion
- Research Requests –Advancing Research and Maximizing the Tissue

Jennifer DeMatteo presented the Technical Procedures Manual Subcommittee Report.

The Technical Procedure Manual Subcommittee submitted the following changes to the Procedures Manual:

The Exam Committee suggested edits:
Page 102
A. The spacing is strange between Alcohol and Preservation under item 1.

B. Sclera must remain in alcohol solution for at least 5 days prior to distribution.
Suggestion – Suggest changing "distribution" to "release for transplant"

Page 94
Under Materials
0.06% Trypan Blue Viscoelastic
Suggestion: Move Viscoelastic to the next line as it is a separate material.

The QA Committee developed a new ***G1.500 procedure on Validation*** for inclusion in the Technical Procedures Manual under G1.000 Quality Assurance.

G1.000 Quality Assurance

G1.500
Validation

Purpose:
To provide an overview of what an eye bank needs to validate in accordance with FDA, EBAA and other appliable standards.

Reference:

- FDA regulations 21 CFR 1271 Human Cells, Tissue, and Cellular and Tissue – Based Products
- EBAA Medical Standards

Glossary:

- *Validation*- The process of demonstrating a specific process or procedure will consistently produce expected results within predetermined specifications.
- *Verification*- The confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
- *Process Validation*- Where the results of processing cannot be fully verified by subsequent inspection and tests, you must validate and approve the process according to established procedures.
- *Documentation*- Providing standard operating procedures to provide general guidance, a process validation master plan that addresses more specific responsibilities, priorities, and schedules, protocols for each specific acceptance criteria, measurements for each validation, then a controlled report for each validation.
- *Software Validation*- Provides objective evidence that the design outputs of a particular phase of the software development life cycle meet all the specified requirements.
- *Installation Qualification (IQ)* - Documented verification that all important aspects of the equipment installation adhere to specifications. Needed when new equipment isinstalled.
- *Operational Qualification (OQ)*- Documented evidence that the equipment performs in accordance with the system specifications throughout operating ranges. Confirmation Equipment operates per manufacturers specifications.
- *Performance Qualification (PQ)*- Establishing documented evidence that the equipment under anticipated conditions produces results for predefined requirements. Performs asspecified.
- *External validation/verification*- Performance of a validation/verification by a contracted third-party supplier.
- *Internal validation/verification*- Performance of a validation/verification by quality personnel.

Materials needed:

- Depends upon what is being validated and what type of validation is being performed.

Procedure	Rationale
1. The following items may be included in the initial validation: a. Validation Report: i. Title – identify the process to be validated. ii. Purpose – the goal of the validation. iii. System description – description of test methodology, identification of equipment, supplies/reagents, include critical steps and effects on other processes. iv. Responsibilities – individuals performing the validation. v. Acceptance/Rejection criteria. vi. Test Results vii. Results summary viii. Review and approval/disapproval	Per EBAA Medical Standards, validation is required for: a) Tissue Processing (E1.200) b) Sterilization (C3.300) c) Tissue Storage (E1.200) d) Assessment of Endothelium (F1.000) e) Labeling (J1.000) Examples of validations for each, but not limited to: a) *Tissues Processing*: transfers, rim cut, EK, LSK, environmental monitoring, etc. b) *Sterilization*: autoclaving, irradiation, ultrasonic cleaning c) *Tissue Storage*: fridge, freezer, shipping containers, preservation media d) *Assessment of Endothelium*: specular, slit lamp e) *Labeling*: statement of sterility if applicable, software validation
b. Installation Qualification/ Operational Qualifications/ Performance Qualification (IQ/OQ/PQ) i. For facilities or equipment validation	FDA 1271.200 Equipment EBAA Medical Standard C3.200
c. Cultures: i. Where there is a risk of contamination/cross-contamination or the introduction of communicable disease, cultures must be obtained. ii. Establish criteria for acceptable culture results. iii. Identify steps in the process where contamination/cross-contamination or the introduction of communicable disease could occur and culture. iv. A validated process should be monitored with in process-cultures being obtained on a regularly scheduled basis.	FDA 1271.220 Processing and Process Controls
2. Changes in validated process: a. Any change to a validated process must be evaluated, verified or re-validated and documented accordingly.	FDA 1271.225 Process Change FDA 1271.230 Process Validation

A motion was made and seconded to approve the two suggested edits. Brian Philippy commented that "release for transplant" was outdated. There was discussion and recommendations on how the language could be improved. Dr. Chamberlain decided that Vicki and her committee would be asked to

come back to the next MAB meeting in the fall with improved language. **The suggested change to page 94 was approved.** A motion was made and seconded to approve G1.500 Validation, to be added to the Technical Procedures Manual. **The motion passed.**

Eric Meinecke presented the Processing Subcommittee Report. Eric directed MAB members to the changes in red to C1.400 Change of Governance, the new table (C1.410 Processing Activity), the glossary text in red for Processing, and Lamellar/Segmental Additive Keratoplasty. A motion was made and seconded to approve the subcommittee's recommendations. Chris Stoeger requested that Irradiation/Sterilization be added in the Advanced (Level II) column for Sclera. Another recommendation was made to drop the T at the end of LSAKT. **Those recommendations were accepted, and the MAB voted to approve the changes to medical standard C1.400 and the glossary.**

C1.400 Change in Governance

An eye bank that undergoes a change in governance must notify the EBAA office, in writing, within 30 days. Some examples of changes in governance include a merger of eye banks, affiliation of two or more eye banks, affiliation of an eye bank with another non-eye bank organization (e.g., tissue banks, organ procurement organizations, hospitals, blood banks, etc.), a change in the name of the eye bank, a change in required personnel, i.e. Director, Medical Director, or ***a change in processing activity.***
(Refer to Accreditation Policies and Procedures E1.500.)

C1.410 Processing Activity is defined as Basic (Level I) and Advanced (Level II) in the following table:

	Basic (Level I)	**Advanced (Level II)**
Cornea	Rim Trim	DSAEK/ALK
	Tissue Rinse	DMEK
	Media Transfer	Preload DSAEK/DMEK
	Corneal Marking (PKP)	Laser Assisted Keratoplasty
	Long-Term Preservation	Irradiation/Sterilization
	Media Additive	LSAK
Sclera	Long-Term Preservation	Irradiation/Sterilization
Whole Eye	Transfer	
	Rinse	
	C-S Rim Removal	

Glossary Terms:

Processing. 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.
Specific processing activities are categorized as Basic (Level I) or Advanced (Level II) according to the matrix in C1.410 Processing Activities.

Lamellar/Segmental Additive Keratoplasty (LSAK). Donor Tissue corneal segments or lamellae derived from any layer of the cornea intended for onlay, inlay or underlay keratoplasty procedures.

Adam Stockman presented the Environmental Monitoring Subcommittee Report. At the Fall 2023 Medical Advisory Board meeting, a subcommittee was formed and tasked with drafting a medical standard addressing environmental monitoring. This subcommittee consisted of Adam Stockman, Dr. Winston Chamberlain, Jennifer DeMatteo, Mike Tramber, Charles Pivoney, John Lohmeier, William Buras, and Kristin Mathes.

The subcommittee felt it best to develop guidance focused on what an eye bank environmental monitoring program needs to address while avoiding specifics on how to address these items, frequency requirements, sample sizes, etc. This approach would allow flexibility for eye banks to develop procedures appropriate for their unique operations. The subcommittee proposed the following text be added to the EBAA Medical Standards (under C3.000 Facilities):

X.XXX Environmental Monitoring

Facilities that perform tissue processing shall have procedures established for environmental controls and monitoring to prevent environmentally introduced microorganisms. Eye banks must adequately control environmental conditions in areas of the facility where processing occurs by providing justification and documentation for the following control activities or systems:

1. *Type and frequency of environmental monitoring*
2. *When samples are taken (e.g., during operations (dynamic) or in a static environment)*
3. *Sample locations and number of sites to be sampled, and duration*
4. *Sample size (e.g., surface area, air volume)*
5. *Action and alert levels for test results with corresponding investigation and corrective actions as defined by SOP.*

Activities must include temperature and humidity controls, ventilation and air filtration, cleaning and disinfecting of rooms and equipment; and maintaining equipment used to control conditions necessary for aseptic processing.

A motion was made and seconded to approve the subcommittee's recommendation. **The motion passed.**

Andrew Officer presented proposed changes to the medical standards from the Accreditation Board's Subcommittee on Training. The proposed changes were to C1.200, C2.000, and the glossary.

C1.200 Medical Director

The eye bank must have a Medical Director. When the Medical Director is not available, a back- up Medical Director shall be designated who is capable of fulfilling the responsibilities of the Medical Director on an interim basis.

The Medical Director and a back-up Medical Director must be an ophthalmologist who has completed a corneal fellowship or who has demonstrated expertise in external eye disease, corneal surgery, research or teaching in cornea and/or external disease. If the Medical Director has not served a corneal fellowship, then the eye bank must have and document a consulting relationship with an ophthalmologist who has.

Any physician who provides ~~verification of~~ competency determination by observation of ~~for~~ staff performing tissue recovery, and preservations, and/or processing shall attend the Medical Directors' Symposium at the annual meeting of the EBAA at least once every three years and a Medical Advisory Board meeting once every three years. A newly appointed Medical Director shall attend a Medical Directors' Symposium and a Medical Advisory Board Meeting within one year of appointment, unless a Co- Medical Director has fulfilled the requirement. The eye bank shall provide written documentation of such attendance at the time of the eye bank site inspection.

For the purposes of this standard, "technician" refers to any individual performing eye bank functions (e.g. recovery, processing, tissue evaluation, donor eligibility determination, storage, and final distribution).

The Medical Director shall oversee and provide advice on all medical aspects of the eye bank operations. These include but are not limited to:

1. Formulation, approval, and implementation of medical policies and procedures.
2. Participation in training and oversight of technical staff with regard to eye bank functions.
3. Participation in establishment and operation of a quality assurance program, including but not limited to policy development and approval, process validation, adverse reaction investigation, donor chart auditing, and development of corrective and preventive action plans.
4. ~~Responsibility for verification of competency for tissue recovery and preservation by personnel applying for CEBT certification~~. Proficiency assessment of personnel applying for CEBT certification.
5. Initial and annual competency determination *by observation* of all staff designated to train tissue recovery, preservation, and processing procedures.
6. Initial and annual competency determination *by observation or verification* of all staff designated to train the functions of tissue evaluation and surgical suitability determination.

7. Initial and annual competency determination *by observation or verification* of all staff designated to release tissue for surgical use (e.g., final donor eligibility determination by Medical Director Designee).
8. When there is no trainer designated for a function, the Medical Director may serve as the trainer.

Medical Director responsibilities of competency determination are also outlined in EBAA Medical Standard C2.000 (table).

~~An eye bank's Medical Director must observe the designated staff trainer or trainers performing the following procedures as applicable on an annual basis:~~

1. ~~In-situ corneoscleral disc excision or laboratory corneoscleral disc removal from whole eye~~
2. ~~Posterior lamellar processing procedure that utilizes a microkeratome~~
3. ~~At least one type of laser-shaped processing procedure~~
4. ~~Each manual dissection processing procedure(s) for EK and ALK (i.e., DSEK or DMEK)~~

~~If an eye bank Medical Director has not designated any individuals as staff trainers he/she must observe each technician they have qualified to perform any of the above procedures on an annual basis.~~

The Medical Director may delegate responsibility for eye bank functions to qualified eye bank personnel; however, the Medical Director shall ensure that the eye bank operates in compliance with the EBAA Medical Standards. Ultimate responsibility for the suitability of each tissue for the transplantation in patients rests with the transplanting eye surgeon.

An eye bank has three months to replace a Medical Director who has resigned.

C2.000 Training, Certification and Competency Reviews of Personnel Performing Tasks Overseen and/or Regulated by the EBAA, FDA, and Other State and Federal Agencies.

An eye bank or other establishment performing eye banking functions must provide a formal orientation program for each new employee and the employee's participation must be documented. For the purposes of this standard, "technician" refers to any individual performing eye bank functions (e.g. recovery, processing, tissue evaluation, donor eligibility determination, storage, and final distribution).

An eye bank or other establishment performing eye banking functions must also establish a comprehensive and well-defined training program outlining specific job-related tasks that each employee is being trained to perform. This comprehensive training program shall include the implementation and documentation of annual competency reviews of the skills and job-related knowledge of all eye bank employees performing eye banking functions. The person responsible for this training program must be a CEBT or an individual who has been qualified by a CEBT who is part of the organization's comprehensive quality program.

Eye bank technicians may independently perform only those activities for which they are qualified and authorized by competency assessment. A competency assessment evaluates or determines an individual's ability to perform a specific task according to procedure. A competency assessment is completed before the individual performs the task independently and at least annually thereafter. ~~Determination of competency~~ Competency determination for eye banking functions is the responsibility of the Medical Director or trainer(s) designated and determined competent by the Medical Director to serve as trainer of a function. Competency determination may be accomplished by observation or verification. Observation and verification are defined in the EBAA Medical Standards Glossary. This training program shall contain documentation indicating when each employee is released to perform their job-related tasks independently. Competency and training records shall be maintained for a minimum of 10 years.

Eye bank technicians seeking to receive EBAA certification or become recertified must meet the criteria set forth in the EBAA document Criteria for Certification and Recertification of Eye Bank Technicians.

All EBAA accredited eye banks must have one CEBT attend an EBAA sponsored skills workshop once every three years.

Initial and Annual Competency Responsibilities		
Procedure	**Trainer**	**Non-Trainer**
Recovery	Observation by Medical Director	Observation by Trainer
Preservation	Observation by Medical Director	Observation by Trainer
Processing	Observation by Medical Director	Observation by Trainer
Tissue Evaluation	Observation or Verification by Medical Director	Observation or Verification by Trainer
Surgical Suitability Determination	Observation or Verification by Medical Director	Observation or Verification by Trainer
Donor Eligibility Determination	Observation or Verification by Medical Director	Observation or Verification by Medical Director

- If a procedure has optional steps (e.g., DMEK processing procedure has optional step for pre-load), a single competency assessment with all optional steps performed shall represent competency assessment of all variations of the procedure.

- Trainers may not determine competency of other trainers.

EBAA Medical Standards Glossary

Competency Assessment – A competency assessment evaluates or determines an individual's ability to perform a specific task according to procedure.

Competency Determination – Determining competency either by observation, verification, or both.

Observation of Competency – The act of viewing a procedure or mock procedure to assess the technician's competency to independently perform the procedure. Observation of competency is one of two methods for assessing competency.

Verification of Competency – The act of reviewing evidence of skilled execution of tasks related to the eye bank function performed to assess the technician's competency to independently perform the p one of two methods for assessing competency.

A motion was made and seconded to approve the changes. **The motion passed.**

Brian Philippy presented changes to J1.000 Labeling:

J1.000 Labeling

All ocular tissue distributed for surgical use shall be in a container which is clearly and indelibly labeled to include at least the information below.

1. *Name of source eye bank.*

2. *ISBT 128 tissue identifier. The ISBT 128 tissue identifier includes the Donation Identification Number (DIN) and Product Code.* ~~*and*~~ *The Donation Identification Number (DIN) includes Processing Facility Identification Number (FIN), year, and sequence number* ~~*Information Code (if applicable)*~~*.*

3. *Type of tissue (e.g., cornea, whole eye, sclera).*

4. *If cornea has had additional processing (e.g., lamellar, laser shaped), clearly indicate this on the label.*

5. *If the Product Code and Donation Identification Number are not assigned by the same entity, then the label must include the Processing Facility Information Code, which includes the Facility-Defined Product Code (FPC) and Processing Facility Identification Number (FIN(P)).*

6. *Expiration date of tissue, in the international format (YYYY-MM-DD).*

7. *A statement that the tissue is intended for single patient application only.*

8. *A statement that the tissue is not to be considered sterile unless tissue has been subjected to a validated process to ensure sterility.*

9. *Type of storage solution.*

10. *ISBT 128 data structures shall be used within two-dimensional (2-D) symbols (Data Matrix) to label ocular tissue products distributed internationally, effective January 1, 2017.*

A motion was made and seconded to approve the changes. **The motion passed.**

Brian Philippy suggested the following changes to L1.100:

L1.100 Tissue Report Form

In special circumstances, like approved research programs, the Medical Advisory Board may waive certain label and tissue report form requirements. Approval for omissions must be obtained in advance from the MAB and surgeons receiving study tissues must consent in advance to any masking of standard required data.

Tissue distributed for transplant use shall be accompanied by a tissue report form and may include additional forms to address all requirements. The tissue report, together with pertinent additional forms shall contain the following:

All Tissues:

1. *Name of (Source) eye bank*
2. *Location of eye bank*
3. *Telephone number of eye bank*
4. *ISBT 128 tissue identifier.*
5. *Type of storage solution*
6. *All dates shall be written as YYYY-MM-DD HH:MM to harmonize with the ISO 8601 requirements.*
7. *If cornea is processed, clearly indicate the type of processing performed or the indicated use (e.g., endothelial keratoplasty, posterior lamellar keratoplasty, anterior lamellar keratoplasty, laser assisted keratoplasty, etc.).*
8. *If the Product Code and Donation Identification Number are not assigned by the same entity, then the label must include the Processing Facility Information Code, which includes the Facility-Defined Product Code (FPC) and Processing Facility Identification Number (FIN(P)).*
9. *Tissue evaluation reporting requirements according to Matrix II.*
10. *Name and EBAA Accreditation Status of each establishment that performs any of the following steps in the preparation of tissue: recovery, processing, storage, evaluation, donor eligibility determination and distribution. Steps performed after release of whole cornea for transplant use (e.g., processing, distribution) may be documented on additional forms (e.g., "processing form", "disclosure of eye banking functions form", importing eye bank revised/supplemental Tissue Report Form, or other documents).*
11. *A summary of records reviewed regarding the eligibility of tissue for transplant.*

A motion was made and seconded to approve the changes. **The motion passed.**

Brian Philippy delivered a report on some Statistical Committee proposed changes to the EBAA Ledger and data system which if approved by the MAB, would be sent to the Board of Directors for ratification before implementation.

Item 1: Add "Donor Type" to section II.
This measure of eye-only, eye/tissue, eye/organ, and eye/tissue/organ donors is useful internally for eye banks, as well as pooled data for the community. A recent example of when this information could have been useful is during the PPRS' consideration of Chagas disease and the nuances of which party is testing. Additionally, this value will be crucial in measuring impact of changes related to regulatory oversight of OPOs, which are likely to be regionally impactful. The data exists in the main donor databases used in the US and should be relatively easy for those vendors to report out for EBAA members. (See attachment regarding proposed addition of II.E.)

A motion was made and seconded to approve adding "Donor Type" to section II. Kristin Mathes commented that if approved, this would require eye banks to update their donor databases. Both time and expense should be considered by the MAB prior to voting. There was discussion on ROI and implementation time. **The motion passed.**

Item 2: Remove PDEK option and add DMAK, "Refractive", and cell therapy options to section V.
Section V is where we measure the use of intermediate-term corneas for transplant.

- PDEK activity remains low - only 3 occurrences in 2023. This warrants ceasing its measure independently from "other EK".
- Descemet's Membrane Anterior Keratoplasty (DMAK) is an emerging ALK procedure as of 2023 and happening currently at a rate similar to KLA, but with a growth profile. "Refractive" is the general term chosen to cover the array of refractive procedures (e.g. CAIRS) using donor tissue.
- "Cell therapy" is the general term chosen to cover the array of emerging cell-cultured procedures (first such use in human trials in the US is already consuming transplant- eligible tissue for presumed transplant-adjacent use)

Additions to section V. are made in V.C. (domestic) and repeated in V.D. (international). (See attachment regarding proposed changes to V.C. and V.D.)

A motion was made and seconded to approve. **The motion passed.**

Item 3: Add "Refractive" to long-term preserved cornea distribution, section VI.B. Section VI.B. is where the distribution of long-term corneas are counted. The current data set includes "keratoplasty", "glaucoma shunt patching", and "other surgical uses". The addition of "Refractive (e.g. CAIRS)" to the options would also be paired with differentiating "Keratoplasty" into "Keratoplasty (non-refractive)". (See attachment regarding proposed changes to VI.B.)

A motion was made and seconded to approve. **The motion passed.**

Implementation Recommendation: January 2025

Edwin Roberts, from the Eye Bank for Sight Restoration, presented revisions to EBAA Medical Standards to ensure consistency with terminology and align with the recent discussion with an infectious disease testing laboratory.

D1.230 Non-Required Testing Results

All non-required positive **or reactive** infectious disease tests must be reported to the eye bank's medical director, who must review and act on them, or the eye bank must have a standard policy regarding the action to be taken in response to the individual test.

G1.300 Tissue Recall or Tissue Withdrawal

Eye banks must have a policy and procedure for potential recall of tissue.

Positive **or reactive** test results or information about behavioral risks or medical history, received after release of tissue, that indicate a risk for transmission of a relevant communicable disease must be reported to the:

- Eye bank's medical director
- Consignee (i.e., the transplanting surgeon, processor or distributing eye bank), within 45 days
- EBAA office, within 45 days
- FDA or other appropriate government agency, within 45 days

Consignee notification of positive **or reactive** results or information that does not indicate a risk of transmission of a relevant communicable disease does not require EBAA notification.

A motion was made and seconded to approve the changes to D1.230 and G1.300. **The motion passed.**

Dr. Chamberlain then asked Jennifer DeMatteo to begin a discussion on FDA beginning to issue some eye banks 483s for not determining donors to be ineligible with a diagnosis of sepsis. A regulatory alert was issued by the EBAA on May 17, 2024. Jennifer explained that the FDA's focus on sepsis and donor eligibility determination is likely related to the two recent Mycobacterium tuberculosis (MTB) outbreaks linked to bone allografts. Jennifer then asked for comments and questions.

Kristin Mathes recommended that a MAB subcommittee be formed to be ready to evaluate the future FDA guidance documents and help develop best practices for eye banks to follow. Kristin called for more consistency across the profession on sepsis screening. Dr. Woody Van Meter shared valuable wisdom and perspective on the topic. He encouraged all eye bank medical directors to not only be aware, but to be heavily involved in helping their eye banks with their donor screening and eligibility procedures. Excellent comments from Dr. Sadeer Hannush, Brian Philippy, and Jason Brosious followed. Several other MAB members shared their thoughts on just how significant an issue this is, as well as offered their ideas for how best to respond. Scott Brubaker commented, "what we see…we [the FDA] act on." Scott said the FDA receives MedWatch reports which prompt them to investigate and review donor records. In medical records they are finding donor eligibility issues and, in some cases, "there is no question, they [the donors] are ineligible." Scott continued by saying that the FDA doesn't look at the number of infections compared to number of transplants. The FDA has a "monitoring system" and it's based on MedWatch reports. The FDA is looking at trends,

establishments, and specific organisms from establishments. Scott encouraged the MAB to work with the FDA when the guidance is released. Scott said receiving comments and feedback that helps improve donor screening will be considered. Dr. Chamberlain said that a subcommittee would be formed, but MAB members do not need to express interest. "We know who you are." The subcommittee will consist of knowledgeable and experienced eye bankers and physicians.

Jennifer DeMatteo reminded the MAB that ZIKV **is no longer an RCDAD** and that eye banks may discontinue screening donors for ZIKV and revise their relevant procedures to reflect this change. Jennifer proposed revising EBAA Medical Standards Appendix I and II.

EBAA Medical Standards Appendix I: FDA Defined Relevant Communicable Disease Agents and Diseases

II. A communicable disease agent or disease meeting the criteria described in § 1271.3(r)(2), but not specifically listed in § 1271.3(r)(1), is relevant if it is one

a. For which there may be a risk of transmission by ***ocular tissue***, either to the recipient of the ***ocular tissue*** or to those people who may handle or otherwise come in contact with the ***ocular tissue***, such as medical personnel, because the disease agent or disease:

i. is potentially transmissible by ***ocular tissue***; and

ii. either (1) has sufficient incidence and/or prevalence to affect the potential donor population (§ 1271.3(r)(2)(i)(B)(1)), or (2) may have been released accidentally or intentionally in a manner that could place potential donors at risk of infection (§ 1271.3(r)(2)(i)(B)(2));

b. That could be fatal or life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to a body structure (§ 1271.3(r)(2)(ii)); and

c. For which appropriate screening measures have been developed and/or an appropriate screening test for donor specimens has been licensed, approved, or cleared for such use by FDA and is available (§ 1271.3(r)(2)(iii)).

d. Examples of RCDADs not specifically listed in § 1271.3(r)(1) as relevant include, but are not limited to:

i. ***West Nile Virus***

ii. ***Sepsis***

iii. ***Vaccinia***

~~**iv. *Zika Virus***~~

EBAA Medical Standards Appendix II: FDA-defined Contraindications to Transplant

~~g. Zika Virus (ZIKV) Infection:~~

~~1. Persons with a medical diagnosis of ZIKV infection in the past 6 months.~~

A motion was made and seconded to approve the changes. **Motion passed.**

Dr. Win Chamberlain thanked the Medical Advisory Board, and a motion was made and seconded to adjourn.

Respectfully submitted,

Eric Meinecke, CEBT
Board Secretary