MEDICAL ADVISORY

The following changes were made at the October 17, 2024, meeting of the Medical Advisory Board and will become effective on **January 1, 2025.**

G1.000 **Quality Assurance**

Each eye bank shall have a formally established quality assurance program. This program shall include:

- Establishment and maintenance of procedures for all functions performed by the eye bank (including review, approval, and revision)
- Monitoring and evaluation of functions through periodic audits by an individual(s) not regularly involved in the processes being monitored
- Identification of problems and complaints relating to activities (receiving, investigating, evaluating, and documenting information relating to eye banking requirements)
- Development of plans for corrective actions, including monitoring for effectiveness

The quality assurance program shall address applicable requirements relating to the following areas:

1. Facilities
2. Environmental control
3. Equipment
4. Supplies and reagents
5. Recovery
6. Processing and processing controls
7. Labeling controls
8. Storage
9. Receipt, pre-distribution shipment, and distribution
10. Donor eligibility determinations, donor screening, and donor testing
11. Tissue evaluation

Each eye bank shall document all aspects of its quality assurance program. Records relating to the quality assurance program shall be maintained for a minimum of ten years. These records shall be made available at the time of site inspection.

The Quality Assurance Program shall establish a system for reporting, documenting, and investigation of deviations. Deviations for distributed tissue relating to eye bank functions must be reported to the federal regulators and EBAA within 45 days of the discovery of the event.

The eye bank's quality assurance program shall include a method for the receiving surgeon to report adverse reactions from the transplantation of corneal, scleral, or other ocular tissue to the distributing eye bank. The distributing eye bank must forward the adverse reaction information to the source eye bank, which made the donor eligibility determination. The source bank must perform an investigation and must report the adverse reaction information within 30 days to the EBAA office for review by the Medical Advisory Board. In accordance with FDA 1271.350, adverse reactions involving a relevant communicable disease must be reported to the FDA within 15 calendar days of receipt of the information if the adverse reaction is fatal, life-threatening, results in permanent impairment or damage or requires medical or surgical intervention. Any adverse reaction or deviation (e.g. MedWatch, HCT/P Deviation) reported to a regulatory public health authority ~~will~~shall~~will~~ also be reported to EBAA concurrently.

The source bank must notify all entities involved in the recovery, processing, storage, distribution, tissue evaluation, and donor eligibility determination of the results of the investigation. Each of the involved entities must maintain documentation of the adverse event and results of the investigation forwarded to it by the source bank.

Infection of a systemic nature that the medical director's investigation determines to be possibly, likely/probable or definitely due to donor tissue must be communicated to all entities that recovered organs or received or recovered tissues from that donor.

An adverse reaction reportable to the EBAA is any communicable or other disease that is possibly, reasonably likely/probable, or definite/certain to have been transmitted by transplantation of donor eye tissue, including infection (as manifested by endophthalmitis, keratitis or systemic disease) and biologic dysfunction (such as immediate endothelial failure, donor corneal dystrophy, malignancy, or evidence suggestive of prior refractive surgery). If systemic infectious disease such as HIV, hepatitis, syphilis, West Nile Virus (WNV), or Creutzfeldt Jakob Disease (CJD) develops in a recipient, whether or not it is suspected to be due to donor tissue, this must be reported to the EBAA office. The Medical Director shall receive and review all adverse reaction reports, documenting any corrective actions he/she determines are indicated.

EBAA Medical Standards Appendix V:
Accredited Eye Banks Not Located in the United States

Introduction

This appendix establishes the requirements for each country or region in which eye banks are subject to EBAA accreditation. The sections are written to address each Medical Standard that is otherwise written for eye banks within the United States. The determination of which regulations apply (e.g. FDA, foreign federal, foreign state, or other) may be made by the Accreditation Board and submitted to the Medical Advisory Board for inclusion in the appendix.

Medical Standards Specific to Canada

D1.100

The eye donor's relevant medical records must be reviewed for:

- EBAA-specific contraindications (Ref. D1.110): and
- Health Canada-defined relevant communicable disease agents and diseases: and
- Other diseases as required by the country of import, if exported outside of the United States

D1.120

Health Canada defines communicable disease agents and diseases considered relevant. Tissue from persons exhibiting risk factors for, clinical evidence of, or physical evidence of relevant communicable disease and high-risk behavior associated with relevant communicable disease must not be used for transplant purposes.

D1.200

The eye donor must be tested according to:

- EBAA testing requirements (D1.210)
- Health Canada testing requirements (D1.220).
- Provincial requirements, if applicable
- Other testing requirements of the country of import, if exported outside of Canada

A review of written results of infectious disease testing shall be received by the eye bank prior to releasing tissue designated for surgical use.

The infectious disease testing laboratory and test kits used must meet Health Canada's regulatory requirements.

If plasma dilution sufficient to affect the results of communicable disease testing is suspected, the donor should be considered ineligible, unless a pre-transfusion or infusion sample drawn up to 7 days before recovery is tested; or an algorithm designed to evaluate volumes administered in

the 48 hours before specimen collection is used, showing that plasma dilution sufficient to affect the results has not occurred.

Eye banks shall use a plasma dilution algorithm which meets Health Canada requirements.

D1.220

Refer to Canadian National Standards and CTO Guidance for donor testing requirements and recommendations. Results must be negative or non-reactive for the tissue to be eligible for transplant except as indicated for syphilis.

G1.000

Each eye bank shall have a formally established quality assurance program. This program shall include:

- Establishment and maintenance of procedures for all functions performed by the eye bank (including review, approval, and revision)
- Monitoring and evaluation of functions through periodic audits by an individual(s) not regularly involved in the processes being monitored
- Identification of problems and complaints relating to activities (receiving, investigating, evaluating, and documenting information relating to eye banking requirements)
- Development of plans for corrective actions, including monitoring for effectiveness

The quality assurance program shall address applicable requirements relating to the following eye bank functions:

12. Facilities
13. Environmental control
14. Equipment
15. Supplies and reagents
16. Recovery
17. Processing and processing controls
18. Labeling controls
19. Storage
20. Receipt, pre-distribution shipment, and distribution
21. Donor eligibility determinations, donor screening, and donor testing
22. Tissue evaluation

Each eye bank shall document all aspects of its quality assurance program. Records relating to the quality assurance program shall be maintained for a minimum of ten years. These records shall be made available at the time of site inspection.

The Quality Assurance Program shall establish a system for reporting, documenting, and investigation of deviations (read as “errors or accidents,” as defined by Health Canada).

Deviations for distributed tissue relating to eye bank functions must be reported to the federal regulators and EBAA.

The eye bank's quality assurance program shall include a method for the receiving surgeon to report adverse reactions from the transplantation of corneal, scleral, or other ocular tissue to the distributing eye bank. The distributing eye bank must forward the adverse reaction information to the source eye bank, which made the donor eligibility determination. The source bank must perform an investigation and must report the adverse reaction information within 30 days to the EBAA office for review by the Medical Advisory Board. In accordance with Health Canada, adverse reactions involving a relevant communicable disease must be reported to Health Canada within 24 hours of receipt of the information if the adverse reaction is fatal, life-threatening, results in permanent impairment or damage or requires medical or surgical intervention.

The source bank must notify all entities involved in the recovery, processing, storage, distribution, tissue evaluation, and donor eligibility determination of the results of the investigation. Each of the involved entities must maintain documentation of the adverse event and results of the investigation forwarded to it by the source bank.

Infection of a systemic nature that the medical director's investigation determines to be possibly, likely/probable or definitely due to donor tissue must be communicated to all entities that recovered organs or received or recovered tissues from that donor.

An adverse reaction reportable to the EBAA is any communicable or other disease that is possibly, reasonably likely/probable, or definite/certain to have been transmitted by transplantation of donor eye tissue, including infection (as manifested by endophthalmitis, keratitis or systemic disease) and biologic dysfunction (such as immediate endothelial failure, donor corneal dystrophy, malignancy, or evidence suggestive of prior refractive surgery). If systemic infectious disease such as HIV, hepatitis, syphilis, West Nile Virus (WNV), or Creutzfeldt Jakob Disease (CJD) develops in a recipient, whether or not it is suspected to be due to donor tissue, this must be reported to the EBAA office. The Medical Director shall receive and review all adverse reaction reports, documenting any corrective actions he/she determines are indicated.

L1.200

A "Package Insert" form that meets the EBAA requirements defined below shall accompany the tissue for transplantation. This form shall include the following:

1. Recommended storage temperature for specific type of tissue (cornea; sclera; whole eye). Specific emphasis on DO NOT FREEZE for corneas.
2. That the surgeon should check for integrity of the seal and immediately report to the eye bank any evidence of possible tampering.
3. For corneas in intermediate-term storage solution, a color change per the manufacturer's guidelines may indicate a change in pH, in which case the tissue should not be used and a report made immediately to the eye bank.
4. Whether pre-surgical microbiologic cultures were performed by the eye bank.

5. The form shall also advise the receiving surgeon that the tissues are delivered with no warranty as to merchantability or fitness for a particular purpose, and that the receiving surgeon is ultimately responsible for judging if the tissue is suitable for use.
6. The form shall advise the consignee that they are responsible for tracking of the tissue recipient's name, unique identification number, age and/or date of birth, diagnosis, date of surgery, location of surgery, type of surgery, and the name of the transplanting surgeon when the tissue is transplanted. This information is needed to track the tissue from the donor to consignee and from the consignee to the recipient.
7. "Infectious disease testing has been performed by a laboratory that meets the applicable requirements of the authority having jurisdiction over that laboratory," as required by Health Canada.
8. That Health Canada approved tests were used for infectious disease testing as required by the Health Canada and EBAA, some of which are approved for pre-mortem blood and that Health Canada approved tests for cadaveric blood were used where available.
9. A list of infectious disease test results for that specific donor.

This information may be included on the eye bank's donor screening form as long as it is easily noticed; otherwise, a separate package insert form is advised.

Glossary

Relevant communicable disease: Any communicable disease relevant to transplantation of tissue in humans as defined by Health Canada regulations, Health Canada guidance documents or Canadian law.

Canadian References

SOR/2007-118 Safety of Human Cells, Tissues and Organs for Transplantation Regulations, September 27, 2022.

National Standard of Canada CAN/CSA Z900.1:22 Cells, Tissues, and Organs for Transplantation: General Requirements, updated December 2022.

National Standard of Canada CAN/CSA Z900.2.4:22 Ocular Tissues for Transplantation, updated December 2022.

Guidance Document for Cell, Tissue and Organ Establishments: Safety of Human Cells, Tissues and Organs for Transplantation, May 31, 2018.

Medical Standards Specific to Saudi Arabia

D2.100

The eye donor's relevant medical records must be reviewed for:

- EBAA-specific contraindications (Ref. D1.110): and
- Saudi Arabia defined relevant communicable disease agents and diseases: (SCOT 5.4.13)

and

- Other diseases as required by the country of import, if exported outside of the Saudi Arabia

D2.120
Saudi Arabia defines communicable disease agents and diseases considered relevant. Tissue from persons exhibiting risk factors for, clinical evidence of, or physical evidence of relevant communicable disease and high-risk behavior associated with relevant communicable disease must not be used for transplant purposes.

D2.200
The eye donor must be tested according to:

- EBAA testing requirements (D1.210)
- Saudi Center for Organ Transplantation (D2.210)
- Other testing requirements of the country of import, if exported outside of Saudi Arabia

A review of written results of infectious disease testing shall be received by the eye bank prior to releasing tissue designated for surgical use. (APP # 1446-04, 6.5)

If plasma dilution sufficient to affect the results of communicable disease testing is suspected, the donor should be considered ineligible, unless a pre-transfusion or infusion sample drawn up to 7 days before recovery is tested; or an algorithm designed to evaluate volumes administered in the 48 hours before specimen collection is used, showing that plasma dilution sufficient to affect the results has not occurred.

The eye bank shall use a plasma dilution algorithm which meets Saudi Center for Organ Transplantation requirements.

D2.210
Refer to Saudi Center for Organ Transplantation for donor testing requirements and recommendations. Results must be negative or non-reactive for the tissue to be eligible for transplant except as indicated for syphilis. (DDP.OSC.005 - 5.4.13 and APP # 1446-04, 6.5)

G1.000
Each eye bank shall have a formally established quality assurance program. This program shall include:

- Establishment and maintenance of procedures for all functions performed by the eye bank (including review, approval, and revision)
- Monitoring and evaluation of functions through periodic audits by an individual(s) not regularly involved in the processes being monitored
- Identification of problems and complaints relating to activities (receiving, investigating, evaluating, and documenting information relating to eye banking requirements)
- Development of plans for corrective actions, including monitoring for effectiveness

The quality assurance program shall address applicable requirements relating to the following eye bank functions:

23. Facilities
24. Environmental control
25. Equipment
26. Supplies and reagents
27. Recovery
28. Processing and processing controls
29. Labeling controls
30. Storage
31. Receipt, pre-distribution shipment, and distribution
32. Donor eligibility determinations, donor screening, and donor testing
33. Tissue evaluation

Each eye bank shall document all aspects of its quality assurance program. Records relating to the quality assurance program shall be maintained for a minimum of ten years. These records shall be made available at the time of site inspection.

The Quality Assurance Program shall establish a system for reporting, documenting, and investigation of deviations. Deviations for distributed tissue relating to eye bank functions must be reported to the federal regulators and EBAA.

The eye bank's quality assurance program shall include a method for the receiving surgeon to report adverse reactions from the transplantation of corneal, scleral, or other ocular tissue to the distributing eye bank. The distributing eye bank must forward the adverse reaction information to the source eye bank, which made the donor eligibility determination. The source bank must perform an investigation and must report the adverse reaction information within 30 days to the EBAA office for review by the Medical Advisory Board. In accordance with the Saudi Center for Organ Transplantation (SCOT) adverse reactions involving a relevant communicable disease must be reported to SCOT.

The source bank must notify all entities involved in the recovery, processing, storage, distribution, tissue evaluation, and donor eligibility determination of the results of the investigation. Each of the involved entities must maintain documentation of the adverse event and results of the investigation forwarded to it by the source bank.

Infection of a systemic nature that the medical director's investigation determines to be possibly, likely/probable or definitely due to donor tissue must be communicated to all entities that recovered organs or received or recovered tissues from that donor.

An adverse reaction reportable to the EBAA is any communicable or other disease that is possibly, reasonably likely/probable, or definite/certain to have been transmitted by transplantation of donor eye tissue, including infection (as manifested by endophthalmitis, keratitis or systemic disease) and biologic dysfunction (such as immediate endothelial failure, donor corneal dystrophy, malignancy, or evidence suggestive of prior refractive surgery). If systemic infectious disease such as HIV, hepatitis, syphilis, West Nile Virus (WNV), or Creutzfeldt Jakob Disease (CJD) develops in a recipient, whether or not it is suspected to be due to donor tissue, this must be reported to the EBAA office. The Medical Director shall receive and review all adverse reaction reports, documenting any corrective actions he/she determines

are indicated.

L1.200
A "Package Insert" form that meets the EBAA requirements defined below shall accompany the tissue for transplantation. This form shall include the following:

10. Recommended storage temperature for specific type of tissue (cornea; sclera; whole eye). Specific emphasis on DO NOT FREEZE for corneas.
11. That the surgeon should check for integrity of the seal and immediately report to the eye bank any evidence of possible tampering.
12. For corneas in intermediate-term storage solution, a color change per the manufacturer's guidelines may indicate a change in pH, in which case the tissue should not be used and a report made immediately to the eye bank.
13. Whether pre-surgical microbiologic cultures were performed by the eye bank.
14. The form shall also advise the receiving surgeon that the tissues are delivered with no warranty as to merchantability or fitness for a particular purpose, and that the receiving surgeon is ultimately responsible for judging if the tissue is suitable for use.
15. The form shall advise the consignee that they are responsible for tracking of the tissue recipient's name, unique identification number, age and/or date of birth, diagnosis, date of surgery, location of surgery, type of surgery, and the name of the transplanting surgeon when the tissue is transplanted. This information is needed to track the tissue from the donor to consignee and from the consignee to the recipient.
16. Infectious disease testing has been performed by an approved laboratory of the Saudi Center for Organ Transplantation.
17. A list of infectious disease test results for that specific donor.

This information may be included on the eye bank's donor screening form as long as it is easily noticed; otherwise, a separate package insert form is advised.

Saudi Center for Organ Transplantation References:

Kingdom of Saudi Arabia, Saudi Health Council: Directory of the Regulations of Organ Transplantation; Saudi Center for Organ Transplantation, 2nd Edition 2014

Ministry of National Guard Health Affairs, Administrative Policy and Procedure – Post-Mortem Human Eye Tissue (Corneal) Donation, Ophthalmology (7530), August 2024

Saudi Center for Organ Transplantation, Standards for Cornea Transplantation Service (CTS)

Department Policy and Procedure; Deceased Possible Donor Management, Policy No. DDP.OSC.005

The following changes were made at the October 17, 2024, meeting of the Medical Advisory Board and will become effective on **June 1, 2025.**

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. The Donation Identification Number (DIN) includes Processing Facility Identification Number (FIN), year, and sequence number.
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~~If the Product Code and Donation Identification Number are not ~~assigned by the same entity,~~ If tissue has undergone additional processing, 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.