



Clinical Process Instruction Manual

Ocular Recovery Documentation and Transport Labelling Instruction

Policy:

Trillium Gift of Life Network (TGLN) ensures all pertinent information with respect to ocular recovery activities is documented as required by Health Canada's *Basic Safety of Cells, Tissues, and Organs Regulations* and according to eye bank requirements. The Tissue Recovery Coordinator (TRC) ensures all information including, but not limited to donor identity, physical exam, and pen light assessment is accurately documented.

TGLN shall provide the tissue retrieval site facility with a record of the ocular tissues retrieved as required.

Documentation of case related activities may be completed in paper or electronic format based on recovery location and timing of case. Documentation must be concurrent to the task being completed.

Process:

1. The TRC obtains the following materials:
 - *Eye Recovery Form CSF-9-80* or equivalent
 - *Eye Recovery Note CSF-9-83 (Exhibit 1)*
 - *Recovered Ocular Tissue Package Insert CSF-9-233 (Exhibit 2)*
 - *Recovered Ocular Tissue Transport Label CSF-9-234 (Exhibit 3)*
 - Indelible ink pen
 - Donor chart or copy of electronic record (not required for research and teaching only donors)
2. The TRC documents pertinent information while conducting the donor chart review. If a patient chart is not able to be located and a chart review not done, this must be documented on the *Eye Recovery Form* or electronic documentation system and a chart request must be sent through to the Clinical Information Coordinators. Exceptions to this will be home deaths or Medical Assistance in Death procedures (MAID), where no hospital chart will be available or requested.
3. The TRC completes the *Eye Recovery Form* or electronic documentation system as thoroughly as possible, ensuring that all sections are fully completed. This must include information pertaining to donor identification; consent; Coroner involvement; date, time and cause of death; current and past medical history; hemodilution; physical assessment and eye exam; blood draw and eye recovery details as applicable; and donor reconstruction and final disposition. The TRC must transcribe all the documentation in the *Eye Recovery Form* into the donor management system and upload a copy into the attachments.
4. The TRC documents "not applicable" or "not available" as required.



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5. The TRC signs off for the recovery of each ocular tissue as documentation that the recovery procedure was performed according to TGLN Clinical Process Instructions.
6. The TRC includes additional, relevant information in the clinical notes and additional information tab in the donor management system. This may include inconsistencies, unusual finding, family requests, any other pertinent case details, or items that may require follow-up.
7. All discrepancies, subsequent investigation, and resolution must be documented in the clinical notes.
8. Any deviations from the CPI's need to be documented in the deviation section.
9. Upon completion of eye recovery, the TRC ensures the *Eye Recovery Note* is completed, signed, and left in the patient's chart. If a patient chart cannot be located, the TRC is required to complete and sign the *Eye Recovery Note* and fax it to the recovery hospital's Health Records department (if recovery occurred at the hospital) upon returning to the Provincial Resource Centre. If recovery occurred at a funeral home, do not leave a recovery note. Additionally, the TRC uploads the document into the patient's TGLN chart.
10. When shipping or delivering the tissues place the *Recovered Ocular Tissue Transport Label* on the outside and the *Recovered Ocular Tissue Package Insert* on the inside of the container.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Eye Recovery Form	CSF-9-80	PRC	PRC	16 years
Eye Recovery Note	CSF-9-83	PRC	PRC	16 years
Recovered Ocular Tissue Package Insert	CSF-9-233	PRC	PRC	16 years
Recovered Ocular Tissue Transport Label	CSF-9-234	PRC	PRC	16 years



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References:

- Health Canada's Basic Safety of Cells, Tissues, and Organs Regulations



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Exhibit 1: Eye Recovery Note



CSF-9-83

Eye Recovery Note

Hospital: _____ Date: _____ TGLN #: _____

Patient Name: _____ MRN: _____

Recovery Staff [print name(s)]: _____

The identity of the patient was verified to match the consent form.

The patient's medical chart was reviewed on-site or remotely via secure log in to determine suitable medical history:

Yes No (potentially due to a lack of access; due to patient transfer) N/A (Research & Teaching case)

A physical assessment of the patient was completed and the eyes were examined for signs of infection, corneal damage, embedded foreign bodies, or previous surgery. N/A (Research and Teaching Only)

Blood was collected from (check where applicable):

subclavian artery, femoral artery, laboratory (pre-drawn sample available), Other If Other, specify- _____ N/A

Tissue recovered (check all that apply): Left Whole Eye Right Whole Eye Left Cornea Right Cornea

Each eyelid was gently opened to thoroughly irrigate the corneas and conjunctival sac with a sterile ophthalmic solution. The operative area was prepped using a povidone-iodine solution, alcohol swabs, and sterile drapes.

An ocular speculum was inserted under the upper and lower lids. Near the lateral edge of the cornea at the limbus, the conjunctiva was grasped with forceps with small scissors pointed away from the cornea and a peritomy was continued 360° around the cornea. The scissors were then inserted under the conjunctiva in order to perform a blunt dissection around the globe.

Type of ocular recovery completed and steps continued for that specific procedure:

<input type="checkbox"/> Enucleation (Whole Globe Recovery)	<input type="checkbox"/> In Situ (Corneal Recovery)
<p>A muscle hook was used to isolate the medial, lateral, superior, and inferior rectus muscles. These muscles were cut with scissors.</p> <p>Enucleation scissors were inserted behind the back of the eye and positioned around the optic nerve. The optic nerve was cut, leaving a small stump.</p> <p>Using a hemostat or forceps, the globe was gently lifted from the socket. The remaining connective tissue was cut, along with the superior and inferior oblique muscles.</p> <p>The globe was gently placed in the eye jar, cornea facing up, with the optic nerve resting on the cotton bed. The jars were sealed and labeled with the patient's information.</p>	<p>A scalpel blade was used to scrape the remaining conjunctival tissue near the limbus with an outward motion to 5mm from the limbus.</p> <p>An incision was made through the sclera using a scalpel blade. Corneal scissors were inserted into the suprachoroidal space to carefully perform a peritomy to complete the scleral incision 360° around the cornea.</p> <p>The corneoscleral rim button was removed by grasping the scleral rim with forceps and keeping it stationary while the ciliary body-choroid and iris were pulled downward and away from the button. Working side to side, adhesions were gently separated away from the corneoscleral button.</p> <p>After separation, the button was transferred to a vial containing corneal storage medium (Opticool-GS). The vial was previously labeled with the patient information.</p>

The above steps were repeated for the other eye (check one): Yes No. If no, please explain: _____
Upon recovery completion, where reconstruction could be completed, a folded piece of gauze and a plastic eye cap was inserted in the socket(s) and the eyelid(s) were closed to restore a normal appearance. Any remaining preparation solution was wiped off using sterile saline or alcohol. 4 x 4 gauze was placed over the closed eyelids and the patient's head was securely wrapped with Kling gauze. Head rest to be left with the donor.

The patient was rewrapped in the shroud and returned to the storage location from which the patient was removed.

Direction to Hospital Staff: Please leave this Eye Recovery Note in the patient's medical chart.

Signature: _____ Date: _____



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Exhibit 2: Recovered Ocular Tissue Package Insert

Recovered Ocular Tissue Package Insert - NOT SUITABLE FOR TRANSPLANT IN CURRENT FORM

This box contains quarantine donated human tissue for transplant. Donor eligibility has not been completed.

Recovery Information		
TGLN Donor ID# _____ Receiving Tissue Bank Donor ID#: _____		
Donor Name: _____ Surname First Name DOB: DD / MM / YYYY		
Source Establishment (Relevant Tissue Bank) Name/Address/Tel: Eye Bank of Canada 340 College Street Suite B100, Toronto, Ontario M5T 3A9 (416) 978-7355		
Retrieval Establishment (Recovery Location) Name/Address/Tel: _____		
Death (<input type="checkbox"/> Asystole/ <input type="checkbox"/> Aortic Clamping/ <input type="checkbox"/> LSA): Date (dd/mm/yy) _____ Time: _____ ET		
Blood Draw: Date (dd/mm/yy) _____ Time: _____ ET If postmortem, collection: <input type="checkbox"/> <u>≤ 47hrs-21.5hrs</u> or <input type="checkbox"/> >21.5hrs <small>Qualifies Does Not Qualify</small>		
Eye Recovery Completed: Date (dd/mm/yy) _____ Time: _____ ET		
Right Side Recovered By: _____		
Left Side Recovered By (if different than right): _____		
Tissue Shipped	Shipped (v)	Tissue Bank Use Received (v)
Right, Whole Globe	<input type="checkbox"/>	<input type="checkbox"/>
Left, Whole Globe	<input type="checkbox"/>	<input type="checkbox"/>
Right Cornea	<input type="checkbox"/>	<input type="checkbox"/>
Left Cornea	<input type="checkbox"/>	<input type="checkbox"/>
Storage Solution		
<input type="checkbox"/> Saline		
<input type="checkbox"/> Optisol		
<input type="checkbox"/> Other _____		
Comments:		

Shipping Information (TGLN Use)		
I hereby verify that I packaged the donor tissue according to TGLN CPis for consent, screening and recovery of deceased donor tissue.		
Print Name: _____		
Packaged Date (DD/MM/YY): _____		
Packaged Time: _____ ET Weight of Wet Ice: _____ lb		
Courier: _____		



Ontario Health
Trillium Gift of Life Network

SECTION: Clinical

ID NO.: CPI-9-514

PAGE: 6 of 7

ISSUE DATE: July 18, 2008

ISSUE.REVISION: 1.14

REVISION DATE: November 29, 2023

APPROVED BY: Tissue Authority

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Exhibit 3: Recovered Ocular Tissue Transport Label



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483 Bay Street South Tower, 4th Floor
Toronto, Ontario M5G 2C9
Telephone (24/7): 1.877.363.8456
Facsimile: 1.866.557.6100

CSF-9-234

TGLN # _____

DONATED HUMAN TISSUE FOR TRANSPLANT

DO NOT X-RAY

KEEP COOL HANDLE WITH CARE

____ LBS OF WET ICE ENCLOSED

Date and Time Packaged: _____

THIS BOX HAS BEEN VALIDATED TO MAINTAIN TEMPERATURE
BETWEEN 2 TO 8°C FOR 39 HOURS FROM DATE AND TIME PACKAGED

TISSUE MUST REMAIN AT OR BELOW 8°C DURING TRANSPORT

RECOVERY FACILITY
(Name/Address/Phone)

DELIVER TO
(Source Establishment)
Eye Bank of Canada
340 College Street Suite B100,
Toronto, Ontario M5T 3A9
Tel: (416) 978-7355; Fax: 1-416-
978-1522



EXEMPT HUMAN SPECIMENS