Swiss Donation Pathway

Cornea donation

Module — 11

Version 2.0 — February 2026

CNDO
Nationaler Ausschuss für Organspende
Comité National du don d'organes

swiss transplant

CONTENT

For the sake of readability, the generic masculine form is used. However, all references to persons apply to all genders. The term 'organ donation' also includes tissue donation, where applicable.

1.0
Introduction

1.1 Background information on cornea transplantation

The first cornea transplantation was performed in 1905 by the Austrian ophthalmologist Eduard Zirm. Today, it is one of the most frequently performed transplantation procedures worldwide.
In Switzerland, more than 1,000 operations of this type are performed each year. Less than half of the corneas used originate from Swiss donors. Between 2018 and 2024, the number of transplants performed rose by 20%, whilst the number of corneas harvested in Switzerland fell by the same percentage. Imports have therefore become more significant (source: Figures on tissue donation and transplantation in Switzerland, Federal Office of Public Health, published on 7 March 2025). To maintain self-sufficiency in transplant tissue in accordance with the recommendations of the EDQM guidelines in Chapter 12.5, measures to promote corneal donation are therefore necessary.

1.2 Objective

The Swiss Conference of the Cantonal Ministers of Public Health (GDK) has commissioned Swisstransplant to draw up guidelines for organ and tissue donation processes, aimed at professionals in organ and tissue donation (FOGS) in hospitals with an intensive care unit accredited by the Swiss Society of Intensive Care Medicine. Present module contains recommendations for the establishment or further development of corneal donation procedures in hospitals in accordance with the current state of scientific knowledge and taking into account legal requirements. The procedures described range from the identification of potential corneal donors to the handover of the grafts to the corneal bank and contribute to improving the quality and safety of the process, thereby ensuring optimal care and preventing the transmission of diseases. Health protection, transparency of the process, traceability of donations and respect for the dignity of the deceased donor and their relatives are priorities in this regard.

1.3 Scope

These recommendations are intended for all persons working in the area of cornea donation and who cooperate with Swisstransplant. However, they do not cover the obligations of corneal banks regarding the control, processing, preservation, storage and distribution of corneas.

This document is based on the following requirements:

- Federal Act on the Transplantation of Organs, Tissues and Cells (Transplantation Act), SR 810.21 of 8 October 2004 (status as of 1st February 2021)
- Federal Ordinance on the Transplantation of Human Organs, Tissues and Cells (Transplantation Ordinance), SR 810.211 of 16 March 2007 (status as of 1st September 2023)

- Guidance issued by the Federal Office of Public Health (FOPH) concerning articles 13, 14, 16–18 and 51 of the Transplantation Ordinance on the the handling of organs, tissues and cells for transplantation (April 2022)
- Service agreement between the Swiss Conference of the Cantonal Ministers of Health (GDK) and Swisstransplant covering the provision of services by Swisstransplant within the scope of the National Committee for Organ Donation (CNDO) for the years 2022–2026
- Guide to the quality and safety of tissues and cells for human application, 5th edition; 2022, European Directorate for the Quality of Medicines and HealthCare (EDQM)
- Minimum Medical Standards Revision 5, 2020, European Eye Bank Association (EEBA)
- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

Similar to organ donation, tissue donation (and therefore cornea donation) is carried out on a free, anonymous and voluntary basis.
The legal and ethical principles relating to organ and tissue donation can be found in the Swiss Donation Pathway (SDP) – Module 1: Legal basis and requirements for organ donation and donor identification.

Please note:
This document sets out requirements and recommendations:
Requirements are of a binding nature and are worded with "must" expressions in order to meet the requirements of the Swiss Transplantation Act.
Recommendations are for information purposes, of a facultative nature and worded with "can" or "may" expressions..

1.4 Responsibilities

Each hospital or institution is free to decide with which eye bank (hereinafter: cornea bank) approved by the FOPH it wishes to enter into a contractual partnership. This decision must be communicated to the donation networks and Swisstransplant to ensure a comprehensive overview of cornea donation activities in Switzerland.

In the context of multi-organ procurement, responsibility for cornea donation lies with the donation coordinator. Depending on how the donation networks are organised, donation coordinators may take on several steps in the process, from searching for donors to checking for contraindications (see Appendix 1: Swisstransplant list of contraindications for cornea donation) and obtaining consent, right through to carrying out the procurement. Staff involved in these processes must be specially trained for the tasks assigned to them.

In accordance with Art. 47 of the Transplantation Ordinance, the local coordination body must ensure that the donation processes, from the identification of potential donors to corneal procurement, are correctly initiated and coordinated. The local coordination is responsible for quality assurance and for the monitoring of these processes.

Corneal donation processes must be described in written guidelines and integrated into the quality management system (QMS) of the hospital or the donation network.

2.0
Basis of cornea donation

2.1 Anatomy of the cornea

The cornea is the transparent window at the front of the eye. It protects the eye and is both light-transmitting and refractive.
The cornea consists mainly of three layers: the epithelium, the stroma and the endothelium. HLA compatibility (HLA = human leukocyte antigen) is only necessary in rare cases, as the cornea is avascular, which reduces the risk of immunological rejection.

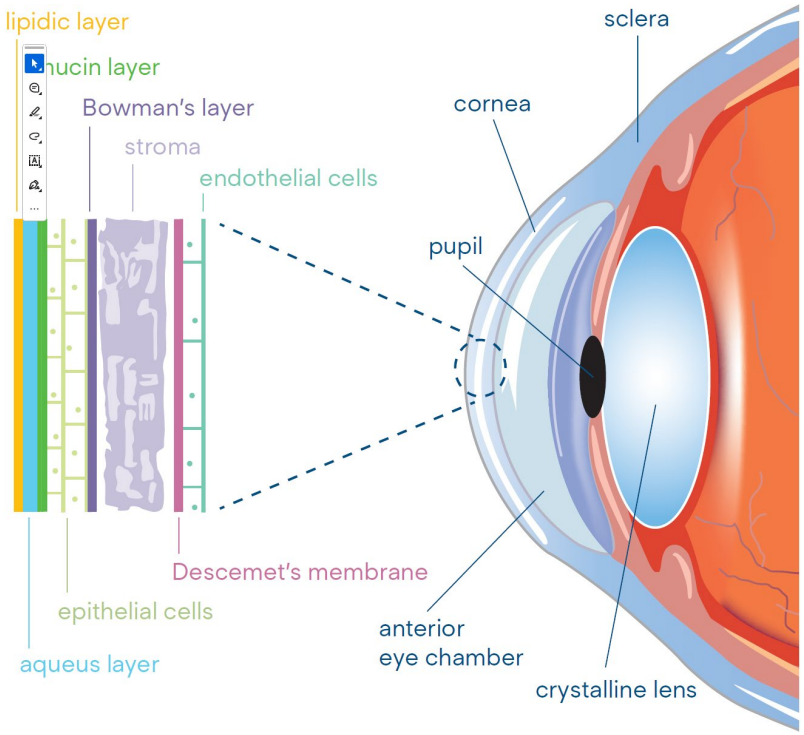

Figure1 : Anatomy of the cornea

2.2 Cornea retrieval

Cornea retrieval can take place either directly as part of a multi-organ donation or from deceased individuals who were not involved in the organ donation process (depending on the banks' recommendations, between up to 24 and up to 48 hours post-mortem). The exact procedure for donation is described in more detail in Chapter3.0 .
Upon arrival at the cornea bank, the cornea is placed in quarantine until the results of the mandatory serological, morphological and microbiological testing are received. Quarantine usually lasts 8 days, although this may be deviated from in urgent cases. In the assessment of the cornea, the determination of cell density plays a particularly important role.
Once the testing has been completed, the cornea is dispatched to the transplant centre within a maximum of one month, in accordance with the cornea bank's guidelines.

2.3 Indications and types of transplantation

The main indications for a transplant are corneal dystrophies (keratoconus), Fuchs' dystrophy (cornea guttata), infectious keratitis, trauma, burns and damage resulting from infection.
Depending on the disease, different types of transplantations are possible (anterior, posterior or full-thickness transplants). The current trend is to limit the transplantation to the layer of the cornea affected by the disease.

Although a cornea transplantation is not a matter of life and death, it can substantially improve patients' quality of life and allow them to return to a normal social and professional life. The graft is often well-tolerated and may even last for more than 20 years. The underlying disease represents the main determining factor for the rejection-free graft survival. In cases where there is a high risk of rejection, systemic immunomodulators may be administered temporarily.

2.4 Quality assurance

The use of donated tissues and cells in the human body can lead to side effects and to the transmission of diseases. This risk can be significantly reduced through rigorous evaluation of donors and the examination of the donated corneas in accordance with the current guidelines.

All stages of the process, from donor identification through to procurement and dispatch to the cornea bank, must be carried out, checked and fully documented by appropriately qualified and specifically trained staff (in procedures, equipment and facilities) in accordance with established standard operating procedures (SOPs). Ideally, the corneal donation process is supervised by donor coordinators, as they are already well familiar with the topic.

A document must be created for each donor, in which all steps of the cornea procurement – from the examination for possible contraindications to the dispatch of the corneas to the cornea bank – are recorded.

We recommend that every hospital maintain a secure, confidential database in which all deceased patients are recorded. This allows the number of potential donors and their suitability for cornea donation to be assessed even outside of active registration hours. To comply with quality and safety standards, an appropriate system must be used that ensures traceability.

3.0
Cornea donation process sequence

3.1 Identification of potential cornea donors

Potential cornea donors can be identified in various ways:

- Systematic search: Staff responsible for identifying potential corneal donors review the records of deceased patients with the support of hospital-specific systems (such as electronic patient records, admissions to mortuaries/mortuary halls, etc.).
- Active reporting of potential cornea donors by the medical staff who had looked after the deceased patient
- Reporting by ward staff or mortuary staff

The capacities and options for identifying potential cornea donors depend on the available personnel resources in the various institutions.

3.2 Assessing suitability for cornea donation

Once a deceased patient has been identified, the assessment of suitability for cornea donation must begin.

3.2.1 Assessing contraindications

Swisstransplant, in collaboration with representatives of the cornea banks, has drawn up a list of minimum contraindications (see Appendix 1: Swisstransplant list of contraindications for cornea donation). The individual cornea banks may apply stricter criteria.

A careful assessment of contraindications must be carried out based on the patient's medical records. The information may be supplemented by the ward doctor, the attending physician, the family or other sources in order to obtain a sound conclusion. If doubts arise in the course of the assessment, the partner cornea bank can be contacted to clarify the donor's suitability.

The assessment of contraindications must be carried out based on a written document issued by the respective institution. The list of contraindications drawn up by Swisstransplant in Appendix 1 serves as the basis for this. In the context of multi-organ procurement, the document "Cornea-DIF-SOAS multi-organ retrieval" must be used (see Chapter6.0).

Unlike most organ transplants, a corneal transplant is not essential for survival. It is therefore all the more important to exercise particular care when selecting donors. It is recommended that the contraindications, and thus the suitability of the deceased person for cornea donation, are checked by two different persons. The second assessment should ideally take place before the procurement. However, it must be done no lather than before the release of the cornea for transplantation.

If no contraindications have been identified, the presumed willingness of the deceased person to be a donor will be assessed. (Chapter3.3). The person in charge ensures that the donor's body is not taken away from the funeral service provider before the procurement of the cornea.

The donor body must be cooled in accordance with the cornea bank's recommendations. This can affect the quality of the corneal grafts.

3.2.2 Unnatural death

If the cause of death is considered unnatural, a permission for the procurement issued by the public prosecutor / judicial authorities is required. The procedure for the permission varies between the different cantons and institutions.

3.3 Assessing willingness for a cornea donation

Communication training and training on the cornea donation process are strongly recommended for the medical staff carrying out this assessment.

All information contained in the patient's medical records relating to a statement on organ and tissue donation must be taken into account (testament/last will, general consent, donor card, etc.). If there are written statements refusing organ and tissue donation, the process is terminated.

If there is no refusal, the relatives must be contacted. In doing so, the order of relatives specified in Article 5 of the Transplantation Ordinance of 16 March 2007 (SR 810.211) must be respected: spouse, registered partner, cohabiting partner; children, parents and siblings; grandparents and grandchildren; other persons who where close to the deceased person.

In case a consent is known, the relatives are informed of the deceased person's wishes and the donation process. If the deceased person has not expressed an opinion on organ and tissue donation, his presumed will must be enquired.

Taking care of relatives and communication are described in Module 2 of the Swiss Donation Pathway. In the case of donors not involved in a multi-organ donation process, the discussion with relatives may be conducted by telephone. It is recommended that the telephone conversation be conducted following a guideline with written notes (e.g. using the document 'Cornea NOK Interview Phone', see chapter6.0).

The relatives should be contacted within a few hours after death to keep the time until cornea removal as short as possible. The possibility of cornea donation and the method of removal (cornea or bulbus removal) should be explained during the conversation (restoration of the intact appearance with closed eyelids). If necessary, the relatives may be granted a reasonable period of reflection. During this discussion, the medical history may be completed if required. If the relatives refuse the donation or cannot be contacted, the process is stopped.

If consent is granted, a consent form for cornea donation must be completed (document "Informed Consent", see chapter6.0 , or the relevant institution's own document). The following details must be provided in this document:

- Date and time of the assessment of willingness to donate
- Name of the person contacted and their relationship to the deceased person
- Name and role of the person conducting the interview
- The decision on authorised removal

In addition, the relatives are given the contact details of the person to contact in case further questions arise.

Regardless of the outcome of the interview, the relatives are thanked and assured that their decision will be respected.

3.4 Retrieval of the cornea

3.4.1 Personnel involved

The procurement must be carried out by an ophthalmologist or by a person specially trained for this procedure. We recommend that corneal removal be carried out by two people. Two people are required because this ensures the proper identification of the deceased person, facilitates the handling of the donor body for the prescribed examinations, and ensures aseptic removal.

3.4.2 Retrieval room

The cornea must be retrieved under aseptic conditions in a location suitable for this purpose. In the case of a multi-organ procurement, it can also be performed directly in the operating theatre. The procurement should be performed in a room where the privacy of the deceased person is strictly protected.
For hygienic and ethical reasons, no other deceased persons should be in the immediate vicinity.

Equipment and requirements for the room (see EDQM guide, Chapters 7.3 and 19.3.3):

- Running water and waste disposal device
- Work surface, trolley, adequate lighting and ventilation to perform the procurement
- Compliance with hospital hygiene standards

3.4.3 Preparation for cornea retrieval

It is important to inform the hospital staff responsible for the donor's body (morgue, operating theatre, wards, etc.) at an early stage as to prevents the funeral service from collecting the donor's body. At the same time, the time and location of the procurement can be scheduled.

Before the procurement, the responsible personnel must check the following points in the patient's medical file respectively ensure that following relevant documents are available:

- No contraindications identified

- Natural death or, in the case of an unnatural death, permission from the relevant legal authority to further proceed.
- Consent for the donation

Planning and preparation for the procurement:

- If an autopsy (medical or judicial) has been requested, arrange for the removal to be prioritised. Blood sampling and cornea removal should ideally take place before the autopsy to allow for blood collection and to reduce the risk of contamination.
- Arrange the time and location for the procurement with the necessary parties
- Prepare the retrieval room
- Organise the transport of the donor's body if necessary
- Depending on the facility's guidelines, a pre-mortem blood sample from the laboratory may be used for all or some of the prescribed serological tests (taken less than 7 days prior to death, provided that no surgical procedure or event posing a risk of contamination has taken place in the meantime)
- Prepare the material for laboratory analysis (see document "Cornea Labtests")
- Prepare and check the chirurgical instruments; prepare the retrieval kit.
- Prepare the transport packaging in accordance with the partner cornea bank's recommendations and inform the bank of the planned procurement.

3.4.4 Cornea retrieval

The donor's body must be treated with dignity and respect by all employees.

Verification of the deceased donor's identity

We recommend that the donor's identity to be verified by two persons by comparing the first name, surname and date of birth on the identification wristband with the donor files (consent form for cornea retrieval, authorisation from the judicial authorities in the event of an unnatural death, and, where applicable with the data within the hospital death register).

To provide evidence that the check has been carried out, a copy of the death certificate must be attached to the donor file.

If any discrepancies arise, the procedure is suspended until these have been clarified. If they persist, the process must be stopped.

Examination of the body surface

This examination is mandatory and must be carried out in accordance with current guidelines. Any suspicious lesion must be reported to the cornea bank.
Particular attention must be paid to the examination of the eyes to identify any possible contraindications.

Blood sample

Swisstransplant lists the blood tests to be carried out (document "Cornea Lab Tests", Chapter6.0), which may be supplemented by additional requirements from the cornea bank. The blood sample must be taken within 24 hours of death, as this is the only way to ensure the quality of the results.

Taking a post-mortem blood sample is not always straightforward. We recommend that the blood sample be taken before the cornea is retrieved. The most common methods here are infraclavicular, intracardiac or femoral puncture. The person responsible for the retrieval of the cornea must possess the necessary expertise and be proficient in these techniques.

Respect for the dignity of the deceased is essential, which is why blood sampling must be carried out with the same care as for a living patient. Surgical preparation of veins to facilitate access for blood sampling should be avoided.

To ensure good analytical quality of the post-mortem blood sample, centrifugation should be carried out as quickly as possible.

The collection tubes are labelled and submitted for analysis in accordance with the agreement and division of labour between the hospitals and cornea banks (for the scope of necessary analyses, see the document "Cornea Labtests", Chapter6.0). The cornea bank is responsible for requesting and checking the results.
In the rare cases where a blood sample cannot be obtained and no pre-mortem sample is available, the process must be stopped.

Retrieval

The retrieval is carried out by a suitably trained employee. We recommend that a second employee assists, completes the file and ensures the aseptic procedure.

The employee performing the retrieval wears a mask, safety goggles, a surgical cap, a gown and sterile gloves. All other persons present wear masks and surgical caps.

There are two collection techniques:

- In-situ corneal harvesting (corneoscleral disc)
- Enucleation

The decision on which technique to use must be discussed with the cornea bank. The procedures for both techniques are outlined below as examples. It is essential to follow the relevant regulations of the partner cornea bank and to document the individual steps of the harvesting process accordingly (procuremen protocol).

<u>Procedure diagram 'In-situ corneal harvesting'</u>

- Rinse the right eye, then the left eye, with 0.9% NaCl
- Rub the eyelids, periorbital area on both sides, the frontal bone, zygomatic bone and nostrils with Betadine soap. Rinse with physiological saline solution and allow to dry
- Disinfect the eyelids, the periorbital areas on both sides, the frontal bone, the zygomatic bone and the nostrils with an aqueous 5% Betadine eye solution (can be prepared using a 10% Betadine Dermicum solution and 0.9% NaCl in a 1:1 dilution)

- Disinfect both eyes, first the right, then the left, twice with 5% Betadine, leaving it on for 2 minutes. Rinse the conjunctival sac of both eyes with 0.9% NaCl
- Apply the sterile drape
- Procedure on the right eye
- Place the eyelid retractor
- Instil 5% Betadine, then rinse with 0.9% NaCl
- Incision of the conjunctival tissue: 360° sclerotomy using a trephine and/or Castro scissors; excision together with a 4 mm circumferential scleral ring
- Detach the iris using forceps
- Place the graft in a transport container (check the temperature, colour of the solution and expiry date beforehand)
- Repeat the same procedure for the left eye, clean the face, close the eyes and restore the integrity of the donor (by fitting a prosthetic cap)

Procedure diagram 'Enucleation'

- Apply gentamicin antibiotic solution to the donor eye
- Eyelid retractor
- Using the forceps from the sterile enucleation set, lift the conjunctiva and separate it in a circular fashion around the cornea (peritomy). Take care not to damage the cornea by applying too much tension with the forceps
- The conjunctiva is bluntly detached from the sclera. This provides access to the insertion points of the eye muscles. Using a strabismus hook, the muscles are gently pulled out
- The muscles are now severed one by one at the outer edge of the strabismus hook
- Gently lift the eyeball using a fixation forceps
- Using blunt, closed enucleation scissors, slide them under the eyeball, open them slightly until resistance is felt, and sever the optic nerve approximately 1 cm before its attachment point. The eyeball can now be removed and placed in one of the plastic containers containing NaCl/gentamicin solution
- The donor's eye socket is filled with a plastic ball, and the eyelids are then closed with two recessed button sutures. This completes the retrieval procedure; alternatively, the eyelids can be closed with adhesive.
- Repeat the same procedure for the other eye

It is recommended that an information document for the funeral service be placed with the donor's body after the procurement. This document should refer to the retrieval and provide the contact details of the responsible persons, and explain that bleeding may occur.

The person performing the retrieval is responsible for restoring the body to an intact appearance.

Labelling, packaging and transport

After retrieval, the corneas must be packaged, labelled and sent to the cornea bank. For transport purposes it is advised to first package the tissue in a sterile and sealed container with the appropriate transport solution and then in secondary packaging

(plastic bag etc.) and finally in outer packaging (sturdy cardboard or similar). The label identifying the corneas must be applied to the first layer of packaging.

The bulbi that have been retrieved are sent to the eye bank for preparation as soon as possible (ideally within the next hour, no later than six hours, as the quality of the corneas will have already begun to deteriorate considerably).

Each cornea bank defines its own recommendations for the packaging, transport and receipt of the corneas.

3.5 After cornea retrieval

Notification to the eye bank:

If this has not already been done during preparation, the bank must be informed of the realized procurement.

Ensuring documentation:

To ensure traceability, the following records must be documented in the donor file (the documents must be retained for 20 years):

- Form for examination of contraindications
- Consent form
- Permission form from the public prosecutor / judicial authorities in the event of an unnatural death
- Procurement report
- Copy of the death certificate

The cornea procurement must also be noted in the patient's medical records. In addition, the hospital's internal list for recording cornea donors must be updated.

Thank-you letters:

It is recommended that a thank-you letter be sent to the relatives.

4.0
Recommendations

4.1 Corneal procurement as part of a multi-organ procurement

We recommend that cornea procurement be carried out in the operating theatre immediately after multi-organ procurement.

The additional serological tests required for cornea retrieval must be requested (HCV-RNA and other tests as recommended by the eye bank). To simplify the retrieval process and improve quality, it is advisable to carry out these serological tests alongside those for organ donation.

The form "CORNEA-DIF-SOAS multi-organ retrieval" must be completed by the donation coordinator and attached to the SOAS. A joint thank-you letter for the organ and tissue donation (corneas) is written.

4.2 Information and training

Ward staff should also be familiar with the subject of cornea donation, as every deceased patient is a potential candidate for cornea donation. All employees must be informed why closing the eyes is important, when cooling must begin, and how to document a cornea procurement in the medical record.
As with organ donation, information and awareness campaigns are needed for cornea donation, based on the principle that "everyone is a potential donor". The aim of these campaigns should be to facilitate decision-making.

5.0
Summary of the cornea donation process

Figure 2 : Cornea donation process flow

6.0
Documents and forms

The following information and instructions are available on the Swisstransplant extranet [10]. If you do not have authorised access, please contact Swisstransplant (cndo@swisstransplant.org)

- Cornea Starter Kit (guidance and practical information on setting up a cornea donation programme)
- Cornea NOK Telephone Interview (guideline on conducting the telephone conversation with relatives)
- Informed Consent (consent from relatives for the donation of organs and tissues)
- Cornea Lab Tests (list of mandatory laboratory tests for a cornea donation)
- CORNEA-DIF-SOAS multi-organ retrieval (mandatory documentation of cornea retrieval as part of a multi-organ retrieval)

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References

[1] Federal Act on the Transplantation of Organs, Tissues and Cells, SR 810.21 of 8 October 2004 (as at 1 February 2021)

[2] Guide to the Quality and Safety of Tissues and Cells for Human Application, 5th edition, European Directorate for the Quality of Medicines & HealthCare (EDQM)

[3] Service agreement between the Swiss Conference of the Cantonal Ministers of Public Health (CMPH) and the Swisstransplant Foundation concerning the provision of services by Swisstransplant within the scope of the National Committee for Organ Donation (CNDO) for the years 2022–2026

[4] Minimum Medical Standards Revision 5, 2020, European Eye Bank Association (EEBA)

[5] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells of 31 March 2004

[6] Ordinance on the Transplantation of Human Organs, Tissues and Cells (Transplantation Ordinance), SR 810.211, of 16 March 2007 (as at 1 September 2023)

[7] Figures on tissue donation and transplantation in Switzerland (admin.ch), Federal Office of Public Health

[8] Guidance from the Federal Office of Public Health on Articles 13, 14, 16–18 and 51 of the Transplantation Ordinance on the handling of organs, tissues and cells for transplantation of 15 November 2017 (as of April 2022)

[9] Swisstransplant Extranet (for registered users only), working documents on the donation process

Changes

Date	Version	Changes
February 2026	2.0	Entire module: New chapter structure and changes/corrections to improve readability Chapter 5.0: Process flow diagram revised Chapter 6.0 Documents and Forms: Newly added References: Updated
February 2023	1.1	Correction
November 2021	1.0	Original version

Appendix 1: Swisstransplant list of contraindications for cornea donation

Mandatory information and examinations EEBA (minimum medical standard, effective from 01.02.2020)

Purpose
The purpose of these standards is to comment on the principles of donor selection, as laid down by Commission Directive 2006/17/EC of 8 February 2006, describing the minimum information required for donor risk assessment and the sources of information that should be documented as part of the donor record.

Information required for donor risk assessment:
- Donor's identity and age
- Cause, time and circumstances of death
- Past and recent medical history
- Behavioural factors that increase the risk of transmissible diseases

Sources of information:
- Medical records
- Attending medical and nursing staff
- Family members or other relevant persons close to the deceased
- Family doctor
- Physical examination of the donor
- Post-mortem report, if available and timely (when an autopsy is performed)

Serological and microbiological testing mandatory for Switzerland
- HIV: HIV 1 + 2 antibody and HIV 1 p24 antigen or HIV PCR
- Hepatitis B: Anti-HBc, HBs antigen. Anti-HBsAg only if Anti-HBc is positive. If the Anti-HBc test is positive and HBsAg is negative, then a positive Anti-HBsAg or a negative HBV PCR is required, along with careful clinical assessment.
- Hepatitis C: HCV Antibody, HCV-RNA (quantitative PCR if in doubt)
- Syphilis: TPHA / TPPA
- Anti-HTLV 1+2
- COVID PCR test, mandatory during a pandemic

Absolute contraindications

The list of contraindications should be used, as each point should be checked for 'in terms of evidence of'.

	Explanation	yes	No	unknown
Death of unknown Aetiology	Cause of death unknown, unless an autopsy provides information on the cause of death after procurement and none of the general exclusion criteria set out in this section apply			
Exposure to toxic substances (lead, mercury, etc.)	Ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may affect the quality of the ocular tissue, or may be transmitted to recipients in a dose that could endanger their health			
Age	Provided that corneas are examined to rule out those with an inadequate endothelium, there is no need to set an upper age limit for donors, but other age-related changes in the cornea must be taken into account. The lower age limit is less clear and will depend on surgical demand			
Blood sample	The interval between cardiac arrest and the collection of a blood sample is over 24 hours (except in the case of pre-mortem blood, taken up to a maximum of 7 days before death (see technical guidelines for ocular tissue EEBA))			

	Explanation	yes	No	unknown
Preservation criteria	It is recommended that corneal preservation takes place as soon as possible after death. All time intervals for each donor (from death to enucleation and preservation) must be recorded. Harvesting of the cornea must take place within 24 hours of death			
Behaviour leading to communicable diseases	Evidence of any other risk factors for transmissible diseases based on a risk assessment, taking into account the donor's social history (e.g. intravenous drug abuse, sexual promiscuity)			
Physical examination of the body	Presence on the donor's body of physical signs implying a risk of transmissible disease(s), such as bruises, lacerations, scars, piercings, needle marks not consistent with recent clinical history, fresh tattoos that may conceal parenteral drug use, and signs of transmissible diseases such as Kaposi's sarcoma, swollen lymph nodes, skin rashes, Jaundice of unknown aetiology, should be interpreted in the context of the donor's medical and social history			
Vaccine with an attenuated virus	Recent history of vaccination with a live attenuated virus where a risk of transmission is considered to exist			
Blood exposure accident	Evidence of any other risk factors for communicable diseases based on a risk assessment			

	Explanation	yes	No	unknown
Evidence of imprisonment for more than 4 days within the last year	Evidence of any other risk factors for communicable diseases based on a risk assessment			
Drug abuse (IV, IM, SC) by the donor or partner in the last 12 months	Evidence of any other risk factors for communicable diseases based on a risk assessment, taking into account the donor's social history (e.g. intravenous drug use, sexual promiscuity)			
Transplantation	Transplantation with xenografts			
Infectious diseases				
Viral	Acute viral encephalitis, disseminated or unknown encephalitis, meningitis, tropical spastic paraparesis			
	Progressive multifocal leukoencephalitis			
	Viral eye diseases (herpes, shingles, chickenpox, HTLV)			
Suspected rabies or infection	Ordinance on Transplantation SR 810.211, Annex 5, para. 2: Assessment of suitability for donation Exclusion of all persons at risk of or suspected of being infected with the rabies virus Systemic infection not controlled at the time of donation, including bacterial diseases, systemic viral infections (such as rabies)			

	Explanation	yes	No	unknown
HIV, hepatitis, HTLV	History, clinical or laboratory evidence of HIV or AIDS, acute or chronic hepatitis B (except in the case of persons with a proven immune status), hepatitis C and HTLV I/II, risk of transmission or evidence of risk factors for these infections			
Congenital rubella				
Jaundice of unknown aetiology				
Covid-19	**Ocular tissue donation: EEBA guideline for donor screening for SARS-CoV-2** The following table is intended to assist eye bank procurement and retrieval staff in their routine donor screening for SARS-CoV-2 and should be used in conjunction with local/regional/national exclusion and deferral criteria determined by competent health authorities, risk assessment instructions from the European Centre for Disease Prevention and Control (ECDC), and the selection/exclusion guidelines in the «ALERT UP-DATE: Coronavirus (COVID-2019) and Ocular Tissue Donation' published by the Global Alliance of Eye Bank Associations (GAEBA). The social history of each potential donor should be included in each individual risk assessment to determine donor eligibility (e.g. including close contact with persons infected with Covid-19, vaccination against Covid-19). With regard to procurement, adequate disinfection of the ocular surface (e.g. with povidone-iodine) is important to inactivate/eliminate enveloped viruses.	yes	no	unknown

	Explanation	yes	No	unknown

SARS-CoV-2 status prior to death	test	donor eligibility
known/available	positive < 14 days before death	not eligible
unknown/not available	post-mortem naso-pharyngeal swab *	↕
known/available	negative	eligible
known/available	positive > 14 days before death	eligible 2 weeks after full recovery and free of symptoms

* In this case, an individual risk assessment is mandatory to decide whether the donor can be accepted or not. Post-mortem nasopharyngeal swabs have not yet been validated. However, the result may be included in the risk assessment.

	Explanation	yes	no	unknown
Bacterial diseases				
Syphilis				

	Explanation	yes	No	unknown
Systemic infection	Systemic infection that is not controlled at the time of donation, including bacterial diseases, systemic viral (such as rabies), fungal or parasitic infections, or significant local infection in the tissues and cells to be donated. Donors with bacterial septicaemia (except for encephalitis and meningitis) may be evaluated and considered for eye donation, but only where the corneas are to be stored using organ culture to allow detection of any bacterial contamination of the tissue			
Fungal diseases				
Fungal sepsis	Even if undergoing treatment (if there is a treated local fungal infection, simply report it on the form)			
Residence in a reported endemic area	Travel and exposure history and local infectious disease prevalence; in this context, in accordance with the Standards for surveillance and epidemic intelligence actions of the European Centre for Disease Prevention and Control, it is important to investigate travel to high-risk regions when taking a social history with regard to new or emerging communicable diseases such as the Ebola virus, Zika virus, novel coronavirus (referred to as 2019-nCoV or Wuhan coronavirus) etc. To find a specific disease risk index for a country, the UK Blood Services Geographical Disease Risk Index, for example, lists the current disease risks for specific countries (www.transfusionguidelines.org) Surveillance and disease data (europa.eu)			

	Explanation	yes	No	unknown
Neurological pathology				
	Dura mater surgery < 1992			
Autoimmune diseases	History of chronic, systemic autoimmune and/or inflammatory disease that could have a detrimental effect on the quality of the tissue to be retrieved; Example: multiple sclerosis, amyotrophic lateral sclerosis and others (e.g. lupus, rheumatoid arthritis, Guillain-Barré syndrome, Alzheimer's disease)			
Treatment with exogenous pituitary hormones < 2000	Recipients of hormones derived from the human pituitary gland (such as growth hormones)			
Neurosurgical procedure performed before 2000 or not documented	Individuals who have undergone undocumented neurosurgery (where the dura mater may have been used).			
Prion diseases	Creutzfeldt-Jakob disease or BSE and antecedents (Syndrome Gerstmann-Sträussler-Scheinker syndrome, kuru, family history of spongiform disease Stayed for at least 6 months in the UK between 1980 and 1996			
Degenerative neurological diseases	People with a history of rapidly progressive dementia or degenerative neurological disease, including those of unknown origin, such as Alzheimer's disease, multiple sclerosis, amyotrophic lateral sclerosis			
Subacute sclerosing panencephalitis				

	Explanation	yes	No	unknown
Neoplastic pathology				
Cancer type	Donors with malignant diseases may be assessed and considered for cornea donation (not for donation of vascularised ocular tissues), except for those with retinoblastoma, haematological neoplasms (such as leukaemia, lymphoma, myeloma), and malignant tumours of the anterior segment of the eye (i.e. primary tumours such as conjunctival intraepithelial neoplasia, squamous cell carcinoma or malignant melanoma, as well as metastases in the anterior ocular segment from other primary malignant tumours). In the case of donors with malignant diseases and a potential risk of metastasis formation in the anterior ocular segment, a thorough slit-lamp examination of the globe or the corneo-scleral disc, focusing on possible metastasis, must be undertaken at the eye bank			
Malignant metastatic melanoma	Malignant melanoma with known metastatic disease also excludes the use of ocular tissue, including avascular cornea			
Liquid cancer	Malignant haematological diseases: myeloma, lymphoma, leukaemia, Hodgkin's disease cured < 5 years, myelodysplasia			

	Explanation	yes	No	unknown
Treatment				
Corticosteroid therapy	As treatment with immunosuppressive agents may invalidate serological antibody tests, a thorough risk assessment is recommended (re-evaluation of all donor information sources, with particular focus on transmissible diseases). In case of uncertainty, PCR/NAT testing for HIV, HBV and HCV may be helpful for a thorough risk assessment			

	Explanation	yes	No	unknown
Risk of haemodilution: see the EEBA haemodilution algorithm for calculation (unless pre-dilution serum is available and is less than 5 days old)	If the donor has received transfusions or infusions within the last 48 hours, the volumes must be recorded and an algorithm applied to assess plasma dilution. Plasma dilution must not exceed 50% if the testing procedures have not been validated for such plasma. According to the EDQM 'Guide for the quality and safety of tissues and cells for human application' [3rd Edition 2017, pages 86–88] the following formula can be used to calculate the respective plasma dilution: Donor total plasma volume = 0.04 [l/kg] * donor body weight Colloids infused within 48 hours prior to death = colloids 48 h [l] Crystalloids infused within 1 hour prior to death = crystalloids 1 hour [l] Total relevant infused volume = colloids 48 h [l] + crystalloids 1 h [l] Acceptable plasma dilution: Total relevant infused volume ≤ Donor total plasma volume or (colloids 48 h + crystalloids 1 h) [l] ≤ (0.04 [l/kg] * body weight [kg]). Explanation: Donor body weight (kg) × 0.04 (l/kg) serves as an estimate of the donor's total plasma volume. The infused volume of colloids (within 48 hours prior to death) and crystalloids (within 1 hour prior to death) is summarised. Their total volume must be less than the estimated donor plasma volume. Eye banks may accept tissues from donors with plasma dilution of more than 50% only if the testing procedures used are validated for such plasma or if a pre-transfusion sample is available weight [kg]			

	Explanation	yes	No	unknown
Ocular pathology				
	Eye diseases and ocular surgery: congenital or acquired disorders of the eye (e.g. herpetic keratitis), or previous ocular surgery, that would prejudice graft outcome (e.g. corneas with previous refractive surgery, or stromal scars, may be acceptable for posterior lamellar keratoplasty)			
	Previous cornea, limbus or sclera transplant			
	Signs of uveitis or conjunctivitis (secretions			
	Herpetic eye infection, ophthalmic shingles (active or past)			

If there are future changes to the EEBA guidelines or the EDQM Guide to Quality and Safety of Tissues and Cells, these will be incorporated into the list.

Literature:
- EEBA minimum medical standard 01.02.2020 Downloads – EEBA
- Guide to the quality and safety of tissues and cells, 4th edition 2019, EDQM (for malignant melanoma)
- Ordinance on the Transplantation of Human Organs, Tissues and Cells, SR 810.211, Switzerland (please note that this text is not available in English), RS 810.211 – Ordinance of 16 March 2007 on the transplantation of organs, tissues and cells of human origin (Transplantation Ordinance) (admin.ch)

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