

THE ROYAL COLLEGE OF OPHTHALMOLOGISTS

GUIDANCE ON THE RETRIEVAL OF HUMAN OCULAR TISSUE USED IN TRANSPLANTATION AND RESEARCH

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1. The purpose of this Guidance

Up to 2500 patients in the United Kingdom benefit each year from ocular tissue transplants. While the overwhelming majority of these are corneal transplants, sclera and ocular stem cells are also transplanted. The successful outcome of these transplants depends not only on surgical and clinical expertise but on the quality of the tissue and, crucially, on the steps taken to minimize the risk of disease transmission from donor to recipient.

1.1. Who the Guidance is for

- This guidance is intended to assist medical and other NHS staff who may be involved in eye donation by setting out the standards that must be met in order for donated ocular tissue to be used for the treatment of patients.

1.2. What the Guidance covers

- The information needed to determine the suitability of a donor according to current government and professional guidance
- Eye retrieval, including the collection of a blood sample and restoring a donor's cosmetic appearance following enucleation
- The responsibilities of individuals and organizations involved in eye retrieval

1.3. Using the Guidance

- Eye banks are obliged under the Department of Health *Code of Practice for Tissue Banks* to have formal, written agreements with donor centres and this document provides the rationale and professional background for such agreements.

1.4. Review of the Guidance

- This guidance will be reviewed at least annually by the Ocular Tissue Transplantation Standards Group (OTTSG), which reports both to The Royal College of Ophthalmologists and to UK Transplant, and updated accordingly on the College website (www.rcophth.ac.uk). OTTSG may be contacted through the College (see Section 11 Contact details for advice and further information).

2. Supply of ocular tissue in the UK

The great majority of ocular tissue transplants in the UK use tissue supplied through the Corneal Transplant Service (CTS), under the auspices of UK Transplant (UKT). The CTS eye banks in Bristol and Manchester receive eyes either directly from donor hospitals or through the other UK eye banks.(Norwich, Moorfields and East Grinstead) Regional transplant coordinator teams are playing an increasingly important rôle in the procurement and donation of eyes. Although this guidance assumes in some sections that eyes from donors are contributed to the CTS eye banks, it is recognized that this is not always the case; but the same principles and standards must still be applied.

The process of donation involves substantial commitment and effort by a number of staff in the donor hospital, including transplant and tissue coordinators, donor liaison nurses, the nursing and medical staff who cared for the donor, patient affairs officers, and mortuary staff. These staff are taking on extra tasks in order to help patients who need ocular tissue: if eyes are not retrieved when offered, their cooperation may be easily lost. If there are difficulties in attending donors, others who are involved should always be kept informed. The Corneal Tissue Act 1986 permits the retrieval of eyes from donors by suitably trained NHS staff who are not registered medical practitioners. The CTS eye banks run training courses for nurses, mortuary staff, and other appropriate hospital staff. Trained non-medical staff provide invaluable support for ophthalmologists in helping to ensure that eyes are retrieved wherever possible. Surgeons who undertake ocular tissue transplantation must also be fully aware of the high standards required in all aspects of eye donation and should provide opportunities for medical staff in training. Queries on policy for retrieval should be directed to the relevant regional representative on the Ocular Tissue Advisory Group (OTAG).

3. Consent

3.1. Consent for transplantation

The Human Tissue Act 1961 (which is currently under review) requires specific consent for donation of tissues for therapeutic purposes. In practice, consent for donation needs to be established with the relatives of the deceased who need to confirm both that the deceased had no known objection to donation and that they also agree to donation.

3.2. Information for relatives

Relatives must be given sufficient and accurate information on which to base their decision, according to the principles set out in *Reference guide to consent for examination and treatment* (Department of Health, March 2001).

3.3. Research consent

While the primary purpose of eye donation will almost always be transplantation, there is also a need for ocular tissue both for research into human eye disease and for teaching purposes. The Human Tissue Act 1961 requires separate consent for these purposes and relatives should be asked to confirm lack of objection to these uses as well as to transplantation.

3.4. Unsuitability for transplantation and disposal of tissue

Relatives should be informed that not every cornea will be suitable for transplantation, but that suitability cannot be determined before the eyes have been collected. Corneas that are unsuitable for transplantation and other parts of the eye may nevertheless be suitable for research. If the tissues are not to be used for either transplantation or research, relatives should be informed that the tissue will be disposed of in a lawful manner.

3.5. Consent for a blood sample and testing

Consent should also be obtained for a sample of the donor's blood to be taken for testing of viral and other microbiological markers of transmissible disease. Relatives should be told that they will be informed of any positive results that may have implications for their own health.

3.6. Consent for seeking further information

Relatives should also be asked for permission to seek further information about a donor's medical history and behavioural background from the donor's GP and other relevant healthcare professionals.

3.7. Record of consent

Oral confirmation by relatives of lack of objection to eye donation is legally sufficient but it is essential to keep a written record of the inquiries made and the outcome. Many hospitals require written confirmation before allowing eye retrieval to proceed. Forms that relatives are asked to sign should be worded in terms of *lack of objection* rather than *consent*.

3.8. Coroner/Procurator Fiscal

When an inquest is to be held in connection with the deceased or when the Coroner or, in Scotland, the Procurator Fiscal requires a post mortem examination of the body, permission must be obtained from the Coroner or Procurator Fiscal before proceeding with eye collection, even though agreement may have already been obtained from the relatives. If in doubt, always check first with the Coroner or Procurator Fiscal before proceeding with eye retrieval.

4. Donor age

4.1. Upper age

Provided that the corneal endothelium is to be carefully examined by microscopy before transplantation to exclude those corneas with low endothelial cell densities, endothelial damage, or other abnormalities, there is currently no need to set an upper age limit for eye donation.

4.2. Lower age

The lower age limit is less certain. Generally, there will be very little demand for corneas from donors under three-years old. For very young recipients, however, there may be an occasional need for corneas from such young donors.

5. *Post-mortem* time

Enucleation should be carried out as soon as possible after a donor's death, but *post mortem* times up to (preferably not longer than) 24 hours are acceptable.

6. Medical and behavioural history

There is an overriding responsibility to recipients to ensure as far as possible the safety and efficacy of donated tissues.

6.1. Providing donor information

- 6.1.1. It is the responsibility of the donor centre and/or local Transplant or Tissue Coordinator to obtain most of the information required to determine the suitability of the donor.
- 6.1.2. The medical and behavioural history of potential donors must be investigated rigorously taking into account current government and professional guidance, and the outcome of the inquiries should be fully documented .
- 6.1.3. The document, *Guidance on the microbiological safety of human tissues and organs used in transplantation*, from the Committee on Microbiological Safety of Blood and Tissues (MSBT) and issued by the NHS Executive, sets out the main microbiological exclusion criteria for tissue and organ donors.
- 6.1.4. The main Medical Contraindications to Donation and Transplantation of Ocular Tissues are listed in Annex 1. This list is kept under regular review.
- 6.1.5. In some instances, based on the information available at the time, it will be clear that a local decision not to proceed with the donation should be made.
- 6.1.6. If there is no immediate reason to exclude the donor and the eyes are to be sent to an eye bank, all required information must be provided in order for the eye bank to be able to determine the suitability of the donor.
- 6.1.7. If the eyes are to be sent to a CTS eye bank, the UKT Ocular Tissue Donor Information Form should be completed as fully as possible by the person retrieving the eyes. Where information is not available at the time the donor is referred to UKT, it should be clearly stated where and how that information is to be obtained, and who will be responsible for collecting the information.
- 6.1.8. It is good practice, and may be required in the Donor Referral Standard agreed between eye banks and donor hospitals or Transplant/Tissue Coordinators, for the person responsible for collecting donor information to complete a Donor Medical History check list , including, where appropriate, the outcome of inquiries to GPs (see Section 1.13).

6.2. Sources of information about donors

These include:

- hospital medical records
- Consultant/Senior Nursing Staff with clinical responsibility for the deceased
- family/most relevant life partner
- GP
- *post mortem* examination request form

6.3. Information required

- 6.3.1. In conjunction with the list of main medical contraindications (Annex 1), information should be sought about the following:
 - Immediate cause of death

- Infusions of blood and fluids. Where infusions have been administered, and a pre-infusion blood sample is not available, complete details of all fluids administered in the 48 hours previous to death and the donor's weight must be recorded in order to be able to estimate the extent of plasma dilution. Plasma dilution of 50% or more may invalidate the serological tests for markers of transmissible disease.
 - HIV, hepatitis and syphilis infection, known or suspected, or high risk behavioural activity
 - Other infectious disease
 - Previous surgery or medical treatment
 - Diseases of unknown aetiology and CNS disorders, including CJD and the risk factors for CJD
 - Malignancies
 - Intrinsic eye disease
- 6.3.2. The most relevant life partner of the donor or, where there is none, a close family member should be interviewed. The person asked to agree to the donation under the terms of the Human Tissue Act 1961 may not be the most relevant to provide information about the donor's medical and behavioural history. The name, contact details, and relationship to the donor of the person(s) interviewed to provide medical and behavioural history should be recorded. The family and relevant life partner must be informed that a sample of the deceased's blood will be tested for HIV, hepatitis B, hepatitis C and syphilis. The family and/or relevant life partner should be asked not only about the deceased's past medical history, but about any behavioural activity that would place the deceased at increased risk of HIV, HBV, or HCV (see Annex 1).
- 6.3.3. The deceased's General Practitioner should be contacted as a potentially important source of information. If it is not possible to do this before the eye retrieval takes place, either the donor centre or the eye bank will subsequently contact the GP. Contact details must therefore be included on the Ocular Tissue Donor Information Form (Annex 3). If the donor centre is to contact the GP, this must be made clear to avoid GPs being contacted twice and written evidence from the GP should subsequently be passed to the eye bank using the GP Donor Information Form .
- 6.3.4. If the donor died in hospital, medical records should be checked and/or the deceased's medical history discussed with the Consultant with clinical responsibility for the patient.
- 6.3.5. If a *post mortem* examination of the donor is pending, the reason for the p.m. request must be ascertained to check that there is not a suspected medical contraindication (e.g., a neurological condition), and the contact details for the p.m. result must be included on the UKT Ocular Tissue Donor Information Form.
- 6.3.6. If a sample of the donor's blood is tested locally, the mandatory tests specified in the MSBT document, *Guidance on the microbiological safety of human tissues and organs used in transplantation*, must be carried out and copies of the test results sent to the Eye Bank.
- 6.3.7. The person responsible for investigating the potential donor's medical and behavioural history must confirm that these standards have been applied, for example by completing fully the required documentation .

7. Eye retrieval

7.1. Eye retrievers

- 7.1.1. Eye retrieval must be carried out by a person who is competent in enucleation. Under the terms of the Corneal Tissue Act 1986, enucleation may be performed by suitably trained NHS staff who are not registered medical practitioners.
- 7.1.2. If the retrieval of eyes is to be performed by someone who was not responsible for obtaining the medical and behavioural background of the donor, the enucleation must not take place until the eye retriever is personally satisfied that consent has been obtained, that all relevant sources of information have been checked, and that where information is awaited, there should be no immediate reason to believe that the retrieval should not take place, especially where there may be an infectious risk to the person retrieving the eyes.

7.2. UKT Ocular Tissue Transport Box

- 7.2.1. The Ocular Tissue Transport Box, which is available through UKT, contains:
 - a set of sterile, single-use instruments with a paper wrapper for use as a drape
 - blood sample tube
 - alcohol swabs for cleaning the skin around the eyes and the eye lids
 - sterile saline for irrigating eyes
 - sterile pots, 25 G needles, eye stands, cotton balls and saline for creating moist chambers
 - eye caps and cotton balls for restoring the donor's appearance
 - an enucleation protocol, a list of medical contraindications, and a UKT Ocular Tissue Donor Information Form.
- 7.2.2. Additional items required include:
 - Ice – at least 1 kg of ice is needed to keep the contents of the transport box below 5°C for up to 24 hours during transport to the eye bank
 - 10-ml syringe and 19 G needle for irrigating the eyes before enucleation
 - 10-ml syringe and 19 G needle for taking the blood sample
 - Sterile gloves and appropriate protective clothing

7.3. Blood sample

- 7.3.1. If the mandatory tests specified in the MSBT document, *Guidance on the microbiological safety of human tissues and organs used in transplantation*, are not carried out locally, a sample of the donor's blood must be sent to the Eye Bank with the donor's eyes.
- 7.3.2. If an ante-mortem blood sample is not available, a blood sample should be taken from the cadaver as soon after death as possible and preferably within 24 hours (i.e., the same time limits as for eye retrieval). The quality of the sample is critical to the reliability of the serological tests for markers of transmissible disease. The blood should be taken from a site away from infusion lines where there is a likelihood of sample dilution. The preferred sites are the brachiocephalic, subclavian or femoral veins.
- 7.3.3. The blood sample should be placed into a tube without anticoagulant.

7.3.4. The sample tube must be clearly labelled with the donor's name, date and one other identifier (e.g., hospital).

7.3.5. The syringe and needle must be disposed of immediately and safely.

7.4. Enucleation and *in situ* excision of corneoscleral discs

7.4.1. A set of sterile, single-use instruments must be used. The instruments must be disposed of immediately and safely after use.

7.4.2. The moist chambers must be labelled clearly with the donor's name, date and one other identifier (e.g., hospital name), indicating left or right eye/cornea.

7.5. Restoring the donor's appearance

7.5.1. The final cosmetic result is of crucial importance both out of respect for the donor and because family or friends may wish to view the body. The orbits should be packed with cotton wool and the lids closed over plastic eye caps to restore the original profile of the lids.

7.6. Packaging, labelling and transport to a CTS eye bank

7.6.1. Labelling

- It is essential that the moist chambers and the blood sample tube are clearly and correctly labelled with the donor's name, date and one other identifier (e.g., hospital name). It should be borne in mind that eye banks may receive in any one day the eyes from several donors. *Absent or incomplete labelling will result in the eyes being discarded owing to uncertainty about donor identification.*

7.6.2. Packaging

- The eyes must be packed in a UK Transplant Ocular Tissue Transport Box with the blood sample, a UKT Ocular Tissue Donor Information Form completed to the best of the eye retriever's knowledge, and any other information that may be available at the time, such as a consent form, a medical history check list, or a GP donor information form.
- The box must be packed according to the instructions provided, including at least 1 kg of ice to ensure correct maintenance of temperature during transport.

7.6.3. Transport

- The box should be closed using the supplied tamper-evident security tag.
- The eye retriever should contact UKT when the eyes are ready for collection, providing specific details of the location and reporting the security tag number. UKT will specify the eye bank address, which should then be clearly written on the label provided and attached to the side of the box. The eyes must be kept at a secure location until they are collected.

8. Responsibilities

8.1. Ocular Tissue Transplantation Standards Group

- To review this Guidance in line with government and professional recommendations, guidance and good practice.

8.2. Ocular Tissue Advisory Group

- To provide advice and support to consultant colleagues and medical staff in training involved with eye retrieval.

8.3. Donor Hospitals/Retrieval Centres

In practice, the following may be undertaken by staff from different hospitals; e.g., the initial approach to a bereaved family is likely to be from medical or nursing staff in the Donor Hospital; Regional Transplant/Tissue Coordinators may undertake investigation of medical/behavioural background, and a member of staff from an eye bank or from another hospital (Retrieval Centre) may collect the blood sample and retrieve the eyes.

- To provide the donor's family and/or most relevant life partner with accurate and relevant information
- To ensure that lack of objection has been established for the purposes of transplantation and/or research
- To ensure that all available sources of medical and behavioural history of the donor have been checked and recorded, including the donor's relatives and/or most relevant life partner
- To obtain a blood sample from the donor and to retrieve the eyes according to this Guidance
- If the eyes are to be sent to a CTS eye bank:
 - To report all relevant donor information to UKT
 - To specify sources of information (e.g., GP, pending *post-mortem* report) that have not been checked and to agree who will be responsible for subsequently obtaining the information
 - To inform UKT immediately of any relevant donor information that is obtained after the donor has been referred to UKT
 - To complete the UKT Ocular Tissue Donor Information Form and to confirm that this standard has been followed
 - To provide copies of test results if the donor's blood sample is tested locally for the markers of transmissible disease specified in the MSBT document *Guidance on the microbiological safety of human tissues and organs used in transplantation*
 - To provide copies of information received from GP's about the donor's medical and behavioural history, if available at the time of referral
 - To notify UKT that the eye retrieval has been completed and to specify a location for collection of the eyes

- To send a letter of thanks to the donor family

8.4. UK Transplant

- To accept donor referrals and to record donor information provided by the donor centre
- To check that all relevant information has been obtained or will be obtained
- To agree who will be responsible for obtaining outstanding information
- To arrange transport of the eyes through its contracted agents to the eye bank
- To provide feedback to the donor centre about use of corneas and/or sclera from local donors
- To notify the donor centre of positive results from tests for markers of transmissible disease that may have health implications for the donor's family and/or most relevant life partner

8.5. Eye Banks

- To receive the eyes and to store the ocular tissue
- To contact GP's and/or pathologists for information not available at the time of referral, if agreed with the donor centre and/or UKT
- To determine the suitability of the donor on the basis of the information provided by the donor centre and the results of tests for markers of transmissible disease
- To determine the suitability of the corneas for transplantation
- To answer specific technical and/or medical queries from donor centres about eye donation and to provide general information about eye and tissue donation for healthcare professionals and the lay public.

This document has been agreed by members of the Ocular Tissue Transplantation Standards Group, June 2004

9. References and bibliography

9.1. Department of Health (including agencies and legal documents)

Human Tissue Act 1961

Corneal Tissue Act 1986

Human Organ Transplants Act 1989

Data Protection Act 1998 (revised)

Guidance on the microbiological safety of human tissues and organs used in transplantation. NHS Executive, 2000 (www.doh.gov.uk/msbt)

Code of Practice for Tissue Banks. Department of Health, 2001 (www.doh.gov.uk/humantissuebanking)

Variant Creutzfeldt-Jakob Disease (vCJD): Minimising the Risk of Transmission. Health Services Circular 1999/178, NHS Executive, 13 August 1999 (www.doh.gov.uk/coinh.htm)

National Blood Service Donor Selection Guidelines (www.transfusionguidelines.org.uk)

9.2. Professional organizations

European Eye Bank Association (www.eeba.net)

- EEBA Standards

British Association for Tissue Banking (www.batb.org.uk).

- General Standards for Tissue Banking
- Guidelines for Tissue Donor Selection
- Technical Guidance for Ocular Tissue Banking

10. Abbreviations

CTS	Corneal Transplant Service
MSBT	Advisory Committee for the Microbiological Safety of Blood and Tissues for Transplantation
OTAG	Ocular Tissue Advisory Group, UK Transplant
OTTSG	Ocular Tissue Transplantation Standards Group, The Royal College of Ophthalmologists
RCOphth	The Royal College of Ophthalmologists
UKT	UK Transplant

11. Contact details for advice or further information

Standards and Advisory Groups

Ocular Tissue Transplantation Standards Group – contact through RCOphth
(Professional Standards)

Ocular Tissue Advisory Group – contact through UK Transplant

Royal College of Ophthalmologists (www.rcophth.ac.uk)

17, Cornwall Terrace,
London NW1 4QW

Tel: 020-7935 0702 Fax: 020-7935 9838

UK Transplant (www.uktransplant.org.uk)

Fox Den Road

Stoke Gifford

Bristol BS34 8RR

Tel: 0117 975 7575 Fax: 0117 975 7577

Chief Executive: Mrs Sue Sutherland (chief.executive@uktransplant.nhs.uk)

Medical Director: Mr Chris Rudge FRCS

Donor Care Director: Miss Sue Falvey

Duty Office manager: Mr. Neil Stapleton

Eye banks

CTS Bristol Eye Bank (www.bris.ac.uk/Depts/Ophthalmology)

Bristol Eye Hospital
Lower Maudlin Street
Bristol BS1 2LX

Tel: 0117 928 4438 Fax: 0117 904 6624

Director: Professor John Armitage (w.j.armitage@bristol.ac.uk)

Medical Advisor: Mr Derek Tole MD, FRCOphth

CTS Manchester Eye Bank

Manchester Royal Eye Hospital
Oxford Road
Manchester M13 9WH

Tel: 0161 276 5623 Fax: 0161 273 6354

Senior Scientist: Dr Irena Reynolds PhD (i.reynolds@man.ac.uk)

Medical Director: Mr Andrew Tullo MD, FRCOphth
(andrew.tullo@cmmc.nhs.uk)

East Grinstead Eye Bank

The Queen Victoria Hospital
Holtye Road
East Grinstead
Sussex RH19 3DZ

Tel: 01342 410 210 Fax: 01342 414106

Coordinator:

Medical Director: Mr Sheraz Daya FRCOphth

Moorfields Eye Bank
Moorfields Eye Hospital
City Road
London EC1V 2PD Tel: 0207 253 1199 Fax: 0207 253 4696

Eye Bank Manager: Dr Sybil Ritten
Medical Director: Mr Frank Larkin MD, FRCOphth

Norwich Eye Bank
Norfolk and Norwich University Hospital
Colney Lane
Colney
Norwich NR4 7UY Tel: 01603 286286 Fax: 01603 288261

Coordinator: Mrs Pam Keeley (Pamela.keeley@norfolk-norwich.thenhs.com)
Medical Director: Mr Chris Illingworth MD, FRCOphth

KeratecEye Bank
Dept. of Anatomy
St. George's Medical School
Cranmer Terrace
London SW17 0RE Tel: 0208 672 1238 Fax: 0208 682 0718

Co-ordinator Ms Deborah Ranby BSc ranby@sghms.ac.uk
Medical Director Mr. Chad Rostron FRCOphth rostron@sghms.ac.uk

Annex 1 Contraindications To Transplantation Of Ocular Tissue

CONTRAINDICATIONS TO OCULAR TISSUE TRANSPLANTATION

These are the main exclusion criteria but the list is not exhaustive and further advice may be required.

1. INFECTIONS

- 1.1 acquired immunodeficiency syndrome (AIDS/HIV)
- 1.2 viral hepatitis (A, B, or C)
- 1.3 seropositivity: HIV, HBsAg, HCV, syphilis¹
- 1.4 behaviour leading to risk of contracting HIV, hepatitis B or C²
- 1.5 viral encephalitis or encephalitis of unknown origin, viral meningitis³
- 1.6 rabies
- 1.7 congenital rubella
- 1.8 tuberculosis
- 1.9 Reyes syndrome
- 1.10 progressive multifocal leukoencephalopathy
- 1.11 septicaemia³
- 1.12 active malaria

2. PREVIOUS SURGERY

- 2.1 receipt of an organ transplant
- 2.2 receipt of dura mater or brain/spinal surgery before August 1992⁴
- 2.3 receipt of human pituitary derived hormones⁴
- 2.4 receipt of a corneal, scleral or limbal graft

3. UNKNOWN AETIOLOGY AND CNS DISORDERS

- 3.1 death from unknown cause⁵
- 3.2 Creutzfeldt-Jakob disease and central nervous system diseases of unknown aetiology (e.g., Alzheimer's disease, other dementias, Parkinson's disease, multiple sclerosis)
- 3.3 Motor neurone disease
- 3.4 Chronic fatigue syndrome (ME)

4. MALIGNANCIES AND PREMALIGNANCIES

- 4.1 leukaemia, lymphoma, myeloma, sideroblastic anaemia, polycythaemia

5. EYE DISEASE

- 5.1 ocular inflammation, including known ocular involvement by systemic disease e.g. sarcoidosis, rheumatoid arthritis
- 5.2 any congenital or acquired disorders of the eye, or corneal refractive surgery that would preclude successful graft outcome
- 5.3 retinoblastoma
- 5.4 malignant tumours of the anterior segment

Notes:

¹ Heavy immunosuppression may invalidate serological screening tests

² High risk behaviour includes:

- having sex with someone who has (or thinks they have) AIDS or who is HIV positive
- men having sex with another man
- working as a prostitute
- injecting drugs, even once
- within the last 12 months:
 - having sex with someone who has participated in the above high risk activities
 - having sex with someone, of any race, living in Africa (except Morocco, Algeria, Tunisia, Libya or Egypt)
 - having sex with someone with haemophilia or other related blood clotting disorder who has received clotting factor concentrates
 - tattooing, acupuncture, ear or body piercing
 - imprisonment

³Viraemia and viral meningitis are absolute contraindications. Bacterial forms of septicaemia or meningitis may be acceptable at the discretion of the eye bank Medical Director but only when the corneas are to be stored by organ culture.

⁴ Increased risk of CJD transmission.

⁵ Death from unknown cause is not a contraindication provided a post-mortem examination is pending and the result will be known before the tissue is transplanted.

June 2004