

The Royal College of Ophthalmologists



Standards for the retrieval of human ocular tissue used in transplantation,
research and training

October 2008

Scientific Department
The Royal College of Ophthalmologists
17 Cornwall Terrace
Regent's Park
London NW1 4QW

Telephone: 020 7935 0702

Facsimile: 020 7487 4674

www.rcophth.ac.uk

© The Royal College of Ophthalmologists 2008 All rights reserved
For permission to reproduce any of the content contained herein please contact events@rcophth.ac.uk

THE ROYAL COLLEGE OF OPHTHALMOLOGISTS

**STANDARDS FOR THE RETRIEVAL OF HUMAN OCULAR TISSUE USED
IN TRANSPLANTATION, RESEARCH AND TRAINING**

Revised September 2008

CONTENTS

| Section | Page |
|--|-------------|
| 1. Purpose of these Standards | 2 |
| 1.1. Who the Standards are for | |
| 1.2. What the Standards cover | |
| 1.3. Using the Standards | |
| 1.4. Review of the Standards | |
| 2. Supply of ocular tissue in the UK | 2 |
| 3. Consent | 3 |
| 3.1. Consent/Authorisation for transplantation | |
| 3.2. Coroner/Procurator Fiscal | |
| 3.3. Information for relatives | |
| 3.4. Research consent | |
| 3.5. Unsuitability for transplantation and disposal of tissue | |
| 3.6. Consent for blood sample and testing | |
| 3.7. Consent for seeking further information | |
| 3.8. Record of consent | |
| 4. Donor Age | 4 |
| 4.1. Upper age | |
| 4.2. Lower age | |
| 5. <i>Post-mortem</i> time | 4 |
| 6. Medical and behavioural history | 4 |
| 6.1. Providing donor information | |
| 6.2. Sources of information about donors | |
| 6.3. Information required | |
| 7. Eye retrieval | 6 |
| 7.1. Eye retrievers | |
| 7.2. NHSBT Human Tissue Transport box | |
| 7.3. Retrieval site risk assessment | |
| 7.4. Donor identification | |
| 7.5. Physical examination of donor | |
| 7.6. Blood sample | |
| 7.7. Enucleation | |
| 7.8. Restoring the donor's appearance | |
| 7.9. Packaging, labelling and transport to CTS eye banks | |
| 8. Responsibilities | 9 |
| 8.1. Ocular Tissue Transplantation Standards Group | |
| 8.2. Ocular Tissue Advisory Group | |
| 8.3. Donor hospitals/retrieval centres | |
| 8.4. UK Transplant | |
| 8.5. Eye banks | |
| 9. References and bibliography | 11 |
| 10. Abbreviations | 11 |
| 11. Contact details for advice and further information | 12 |
| Annex 1. Contraindications to ocular tissue transplantation | 13 |
| Annex 2. Enucleation protocol | 15 |

1. Purpose of these Standards

More than 2500 patients in the United Kingdom benefit each year from ocular tissue transplants. While the overwhelming majority of these procedures 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, critically, on the steps taken to minimize the risk of disease transmission from donor to recipient.

1.1. Who the Standards are for

- These standards are 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 Standards cover

- Consent for the removal and use of ocular tissue from deceased donors
- The information needed to determine the suitability of a donor according to current government regulations 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 Standards

- Eye banks are obliged under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Quality and Safety Regulations), which transposed the EU Tissues and Cells Directive into UK law, to have written third party agreements (TPA) with donor centres and this document provides the rationale and professional background for such TPAs.

1.4. Review of the Standards

- These standards will be reviewed at least annually by the Ocular Tissue Transplantation Standards Group (OTTSG), a sub-committee of the Professional Standards Committee of the Royal College of Ophthalmologists (RCOphth) and updated accordingly on the RCOphth website (www.rcophth.ac.uk). The OTTSG sub-committee may be contacted through the RCOphth (see Section 11 for contact details) for advice and further guidance.
- A competency framework for tissue donation and retrieval is available through NHS Blood and Transplant Tissue Services. Module 9 of this framework deals specifically with competency to undertake eye retrieval.

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), a division of NHS Blood and Transplant (NHSBT). The CTS eye banks in Bristol and Manchester receive eyes either directly from donor hospitals or through other UK eye banks. Donor Transplant Co-ordinators, Tissue Co-ordinators and other specially trained NHS staff are responsible for obtaining lawful consent for the donation, storage and use of ocular tissue and for providing information about the medical and behavioural history of eye donors. Although these standards assume 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, 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 easily be lost. If there are difficulties in attending donors, others who are involved should always be kept informed. Trained non-medical staff provide invaluable support for ophthalmologists in helping to ensure that eyes are retrieved wherever possible. The CTS eye banks run training courses in eye retrieval for nurses, mortuary staff, and other appropriate hospital staff. 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 UKT Ocular Tissue Advisory Group (OTAG).

3. Consent

3.1. Consent/authorisation for transplantation

The Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 (HT Acts) require specific consent/authorisation for the donation and storage of tissue for transplantation and other specified purposes, including research, education or training, quality assurance and clinical audit. If a person has expressed a wish to be an eye donor, for example through the National Organ Donor Register or in a will, that consent is paramount and cannot be overridden by relatives. In the absence of prior consent given by a potential donor, consent may be given by a nominated representative of the donor or by a person in a qualifying relationship/nearest relative. There are some differences between the two HT Acts and it is important that consent/authorisation is obtained according to the relevant legislation.

3.2. Coroner/Procurator Fiscal

If the death has been referred to a Coroner/Procurator Fiscal, permission from the Coroner/Procurator Fiscal must be obtained in addition to the consent/authorisation mentioned in Section 3.1 before proceeding with eye retrieval. If in doubt, always check first with the Coroner/Procurator Fiscal before proceeding with eye retrieval.

3.3. Information for relatives

Relatives must be given sufficient and accurate information on which to base their decision.

3.4. 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 education or training. The HT Acts require separate consent/authorisation for these purposes and relatives should always be asked about these additional uses of tissue.

3.5. 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 and other parts of the eye that are unsuitable for transplantation may nevertheless be suitable for research or education/training. If the tissue is not going to be used, relatives should be informed that the tissue will be disposed of in a lawful manner according to the HT Acts.

3.6. Consent for a blood sample and testing

Consent should also be obtained for a sample of the donor's blood to be taken for the 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.

3.7. Consent for seeking further information

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

3.8. Record of consent

It is strongly recommended good practice that consent is recorded by a specially trained healthcare professional, such as a Transplant or Tissue Co-ordinator, using the NHSBT Consent/Authorisation forms and Management Process Document or their equivalent. This is a requirement of the TPA governing the retrieval of eyes to be sent to the CTS eye banks. If consent is taken over the telephone, the relatives should still be asked all of the questions on the NHSBT form and their answers recorded on the form by the healthcare professional. The names of the person giving consent and of the healthcare professional obtaining consent must always be recorded correctly and legibly.

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; however, tissue from such young donors may be important for other uses such as limbal stem cell transplants.

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. **It is a statutory requirement of the Quality and Safety Regulations that the blood sample must be taken within 24 hours of death.**

6. Medical and behavioural history

There is an overriding responsibility to recipients to assure as far as possible the safety and efficacy of donated ocular tissue.

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 these inquiries should be fully documented. It is strongly recommended that the NHSBT Patient Assessment form is used to record the family interview and that the NHSBT GP form is used to obtain information from

the donor's GP. It is a requirement of the CTS Eye Bank TPA that these forms or their equivalent are used when eyes are to be sent to the CTS eye banks.

- 6.1.3. The main Medical Contraindications to Donation and Transplantation of Ocular Tissue are listed in Annex 1. This list is kept under regular review but is by no means exhaustive. Further advice may be sought from the eye banks and from the UK Blood Services Tissue Donor Selection Guidelines – Deceased Donors (www.transfusinguidelines.org.uk).
- 6.1.4. 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.
- 6.1.5. 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.
- 6.1.6. If the eyes are to be sent to a CTS eye bank, the UKT Ocular Tissue Donor Information form must 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.

6.2. 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. With reference to 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, HTLV or syphilis infection, known or suspected, or behavioural activity that would put the donor at risk of acquiring these infections
 - Other infectious disease
 - Previous surgery or medical treatment, including organ or tissue transplants and past history of transfusion.
 - Diseases of unknown aetiology and CNS disorders, including CJD and the risk factors for CJD
 - Malignancies
 - Eye disease or ocular surgery
- 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 give consent/authorisation to the donation under the HT Acts may not be the most relevant person 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, HTLV 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, HCV, or HTLV (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. 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 NHSBT GP form .
- 6.3.4. If the donor died in hospital, medical records, if available, should be checked and/or the deceased's medical history discussed with the Consultant that had 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).
- 6.3.6. If a sample of the donor's blood is tested locally, the mandatory tests for HIV, HBsAg, HBc, HTLV and syphilis must be carried out only by an accredited test laboratory.
- 6.3.7. The person responsible for investigating the potential donor's medical and behavioural history must confirm that these standards have been applied by completing fully the required documentation.

7. Eye retrieval

A competency framework for eye donation and retrieval is available from NHSBT.

7.1. Eye retrievers

- 7.1.1. Eye retrieval must be carried out by a person who is competent in enucleation.
- 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/authorisation has been obtained, that all relevant sources of medical 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. NHSBT Human Tissue Transport box

- 7.2.1. The NHSBT Human Tissue Transport box (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
 - enucleation protocol, list of medical contraindications, NHSBT Ocular Tissue Donor Information and Retrieval Site Risk Assessment forms.

- 7.2.2. Additional required items not included in the transport box:
- 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 transportation to the eye bank
 - 10-ml syringe and 19 G needle for taking the blood sample
 - Sterile gloves and appropriate protective clothing

7.3. Retrieval site risk assessment

- 7.3.1. It is a requirement that a risk assessment is carried out to ensure that the retrieval site is suitable and appropriate for the removal of tissue from a deceased donor. This focuses principally on the need to be able to treat a donor with dignity and respect as well as quality and safety issues.
- 7.3.2. The risk assessment should be documented and to this end an NHSBT Tissue Retrieval Site Risk Assessment form is provided with the enucleation kit in the NHSBT Human Tissue Transport Box. This risk assessment must be carried out for every eye retrieval as circumstances may change even within the same premises.

7.4. Donor identification

- 7.4.1. Correct identification of the donor is critical to avoid illegally removing tissue from a cadaver without consent and without any investigation of medical or behavioural history.
- 7.4.2. It is strongly recommended good practice for identification of the donor to be confirmed by the eye retriever and another person, such as mortuary staff, hospital site manager, nursing or medical staff. If the donor is not in a hospital or hospice, confirmation of identification will have to rely on, for example, care home staff, funeral directors, and the donor's relatives.
- 7.4.3. In hospitals and hospices, the donor should be identified by the wrist or ankle tag using name, date of birth, hospital number and any other available identifiers. The means of identification and persons confirming identification should be recorded.

7.5. Physical examination of the donor

- 7.5.1. It is a requirement of the Quality and Safety Regulations that a physical examination of the donor is undertaken.
- 7.5.2. It is appreciated that eye retrievers are likely to be working alone and the extent of such a physical examination will be limited, especially as some eye donors are dressed. However, the eye retriever should examine those parts of a donor's body that are readily accessible, noting the areas examined and findings such as tattoos, piercings and scars on the body map provided on the NHSBT Ocular Tissue Donor Information form.

7.6. Blood sample

- 7.6.1. If the mandatory blood tests for transmissible disease are not carried out locally, a sample of the donor's blood must be sent to the eye bank with the donor's eyes.
- 7.6.2. If an ante-mortem blood sample taken not more than 7 days before death is not available, a blood sample should be taken from the deceased as soon after death as possible and not more than 24 hours after death. This is a statutory requirement of

the Quality and Safety Regulations. 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.

- 7.6.3. The blood sample should be placed into the provided tube without anticoagulant.
- 7.6.4. The sample tube must be clearly labelled with the date, donor's name, date of birth, and one other identifier (e.g., hospital).
- 7.6.5. The syringe and needle must be disposed of immediately and safely.

7.7. Enucleation

- 7.7.1. A standard enucleation protocol, such as that provided in the NHSBT Human Tissue Transport Box (see Annex 2) should be followed.
- 7.7.2. A set of sterile, single-use instruments must be used. The instruments must be disposed of immediately and safely after use.
- 7.7.3. The moist chambers must be labelled clearly with the date, donor's name, date of birth and one other identifier (e.g., hospital name), indicating left or right eye.

7.8. Restoring the donor's appearance

- 7.8.1. The final cosmetic result is of critical 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. Any bleeding from the sockets or bruising around the orbits following enucleation should be recorded on the body map (see section 7.5).

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

7.9.1. Labelling

- It is essential that the moist chambers and the blood sample tube are clearly and correctly labelled with the date, donor's name, date of birth and at least 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 may result in the eyes being discarded owing to uncertainty about donor identification.*

7.9.2. Packaging

- The eyes must be packed in an NHSBT Human Tissue Transport Box with the blood sample, NHSBT Retrieval Site Risk Assessment form, an NHSBT 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 an NHSBT GP 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.

7.9.3. 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 these Standards in line with statutory requirements, and government and professional recommendations, guidance and good practice. To develop and provide standards for the retrieval, storage and transplantation of the cornea, sclera and all other ocular and non-ocular tissues into the human eye, including collection of data on the outcome of such procedures, and the distribution of such tissue for research.

8.2. Ocular Tissue Advisory Group

- To maintain the standards of ocular tissue transplantation, eye donation and retrieval. To provide advice and support to consultant colleagues and medical staff in training involved with eye donation, retrieval and transplantation. To consider operational aspects of transplantation including eye retrieval, allocation and data analysis and to monitor activity and outcome. To recommend, as necessary, changes to the nationally agreed protocols, to recognise clinical governance issues and ensure, as far as possible, that national standards of good practice are in place with regard to waiting list criteria and organ allocation that provide equity of access to transplantation. To liaise as necessary with the British Transplantation Society and other bodies in the development of national standards.

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 obtain consent and 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 lawful consent/authorisation has been obtained for the removal, storage and use of ocular tissue.
- 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 these Standards
- If the eyes are to be sent to a CTS eye bank:
 - To comply with the CTS Eye Bank Third Party Agreement signed by the eye retriever's employing Trust/Board or other NHS organization. The CTS Eye Banks cannot accept eyes from Donor Centres that have not signed the TPA.
 - 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 NHSBT Ocular Tissue Donor Information form and Retrieval Site Risk Assessment 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 mandatory markers of transmissible disease.
 - To provide copies of the Consent/Authorisation form, the Patient Assessment form and, if available, the GP questionnaire.
 - 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 in accordance with the UKT Donor Care Policy.

8.5. Eye Banks

- To receive the eyes and to store the ocular tissue
- To contact GPs 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.

These standards were approved by the Ocular Tissue Transplantation Standards Group, June 2008

9. References and bibliography

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

Human Tissue Authority (www.hta.gov.uk)

- Human Tissue Act 2004
- Human Tissue (Scotland) Act 2006
- Human Tissue (Quality and Safety for Human Application) Regulations 2007
- EU Tissues and Cells Directive (2004/23/EC)
- EU Commission Directive (2006/17/EC)
- EU Commission Directive (2006/86/EC)
- Human Tissue Authority Directions 001/2006
- Human Tissue Authority Directions 002/2007
- Human Tissue Authority Codes of Practice

Data Protection Act 1998 (revised)

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)

UK Blood Services Tissue Donor Selection Guidelines – Deceased Donors (www.transfusionguidelines.org.uk)

9.2. Professional organizations

Royal College of Ophthalmologists

European Eye Bank Association (www.eeba.net)

- EEBA Standards

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

British Transplantation Society

10. Abbreviations

| | |
|---------|--|
| CTS | Corneal Transplant Service |
| HTA | Human Tissue Authority |
| HT Acts | Human Tissue Act 2004 and Human Tissue (Scotland) Act 2006 |
| NHSBT | NHS Blood and Transplant |
| OTAG | Ocular Tissue Advisory Group |
| OTTSG | Ocular Tissue Transplantation Standards Group |
| RCOphth | Royal College of Ophthalmologists |
| TPA | Third Party Agreement |
| UKT | UK Transplant |

11. Contact details for advice or further information

Human Tissue Authority (www.hta.gov.uk)

Finlaison House
15-17 Furnival Street
London EC4A 1AB Tel 020 7211 3400 Email enquiries@hta.gov.uk

Standards and Advisory Groups

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

Mr Francisco C Figueiredo, MD, PhD, FRCOphth (Chair)

Ocular Tissue Advisory Group – contact through UK Transplant

Mr Stephen B Kaye, MD, FRCOphth (Chair)

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

17, Cornwall Terrace,
London MW1 4QW Tel: 020-7935 0702

UK Transplant (www.uktransplant.org.uk)

Fox Den Road
Stoke Gifford
Bristol BS34 8RR Tel: 0117 975 7575

Eye banks (HTA licensed)

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 (derek.tole@ubht.nhs.uk)

CTS Manchester Eye Bank

Manchester Royal Eye Hospital
Oxford Road
Manchester M13 9WH Tel: 0161 276 5623 Fax: 0161 273 6354

Manager: Dr Isaac Zambrano PhD (isaac.zambrano@cmmc.nhs.uk)
Medical Advisor: Mrs Fiona Carley FRCOphth (fiona.carley@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

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

Medical Director: Mr Stephen Tuft MD, FRCOphth

ANNEX 1. Contraindications to ocular tissue transplantation

These are the main exclusion criteria, but the list is not exhaustive and further advice may be required (www.transfusionguidelines.org.uk). Check www.rcophth.ac.uk for updates.

1. INFECTIONS

- 1.1 acquired immunodeficiency syndrome (HIV/AIDS)
- 1.2 viral hepatitis (A, B, or C)
- 1.3 HTLV
- 1.4 seropositivity: anti-HIV, HBsAg, anti-HBc (if anti-HBs <100 IU/L), anti-HCV, anti-HTLV, syphilis
- 1.5 behaviour leading to risk of contracting HIV, hepatitis or HTLV¹
- 1.6 tattoos and body piercing within the 6 months before death²
- 1.7 acupuncture within the 6 months before death³
- 1.8 imprisonment within the 12 months before death⁴
- 1.9 bleeding disorders treated with blood-derived coagulation concentrates⁵
- 1.10 viral encephalitis or encephalitis of unknown origin, viral meningitis⁶
- 1.11 rabies
- 1.12 congenital rubella
- 1.13 tuberculosis
- 1.14 Reyes syndrome
- 1.15 progressive multifocal leukoencephalopathy
- 1.16 septicaemia⁶

2. PREVIOUS SURGERY/MEDICAL TREATMENT

- 2.1 immunosuppression⁷
- 2.2 receipt of an organ transplant^{7,8}
- 2.3 receipt of dura mater or brain/spinal surgery before August 1992⁸
- 2.4 receipt of human pituitary hormones⁸
- 2.5 receipt of a cornea, sclera or other human tissue allograft⁸

3. Unknown AETIOLOGY AND CNS DISORDERS

- 3.1 death from unknown cause⁹
- 3.2 Creutzfeldt-Jakob disease¹⁰ and central nervous system diseases of unknown aetiology (e.g., Alzheimer's disease, other dementias, Parkinson's disease, multiple sclerosis, motor neurone disease)

4. MALIGNANCIES

- 4.1 leukaemia, lymphoma, myeloma, polycythaemia (unless confirmed as secondary polycythaemia), sideroblastic anaemia and myelodysplastic syndrome

5. INTRINSIC EYE DISEASE

- 5.1 active ocular inflammation/uveitis
- 5.2 any congenital or acquired disorders of the eye, or previous ocular surgery (including corneal laser surgery), that would preclude successful graft outcome
- 5.3 retinoblastoma
- 5.4 malignant tumours of the anterior segment

Notes:

¹ The Department of Health Blood & Tissue Safety Entry excludes donors that:

- thought they needed a test for HIV/AIDS, HTLV or hepatitis.
- are HIV positive
- are HTLV positive
- are a hepatitis B carrier
- are a hepatitis C carrier
- are a man who has ever had oral or anal sex with another man, even if you used a condom or other protective
- have ever received money or drugs for sex
- have ever injected, or been injected with, drugs; even a long time ago or only once. This includes bodybuilding drugs. Donation may be possible if a doctor prescribed the drugs.
- have had sex within the last 12 months (even if you used a condom or other protective) with
 - a partner who is or thinks they may be:
 - HIV or HTLV positive
 - a hepatitis B carrier
 - a hepatitis C carrier.
 - **(if a woman):** a man who has ever had oral or anal sex with another man, even if they used a condom or other protective
 - a partner who has ever received money or drugs for sex
 - a partner who has ever injected, or been injected with, drugs: even a long time ago or only once. This includes bodybuilding drugs. This may not apply if a doctor prescribed the drugs.
 - a partner who has or may have been sexually active in parts of the world where HIV/AIDS is very common. This includes most countries in Africa.

² Tattoos and body piercing have transmitted infections. Allowing for a period of 6 months helps to ensure that infections tested for will be detected.

³ Acupuncture has transmitted infections. Allowing for a period of 6 months helps to ensure that infections tested for will be detected. If the acupuncture was performed by a suitably qualified healthcare professional on NHS premises, by a registered medical practitioner or registered nurse, or if a valid certificate is available from a registered acupuncturist, the donor need not be excluded.

⁴ A deceased person cannot answer questions about 'at risk behaviour' that may have occurred while in prison and relatives are unlikely to know. Being held in a police cell for less than 96 hours may not exclude the donor.

⁵ Treatment with blood-derived coagulation concentrates are very likely at risk of having transfusion acquired infections. Sexual partners of persons that have received blood-derived coagulation concentrates should not donate tissue if less than 6 months since last sexual contact.

⁶ Viraemia 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.

⁷ Immunosuppression invalidates the serological tests for markers of infectious disease such as HIV.

⁸ Increased risk of CJD/vCJD transmission.

⁹ 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.

¹⁰ Covers individuals with CJD (sporadic, familial or iatrogenic) or variant CJD, and individuals identified as being at risk of CJD/vCJD.

ANNEX 2. Enucleation protocol

Only single-use instruments are to be used.

This protocol assumes use of an enucleation kit as provided in the NHSBT Human Tissue Transport box, which is available free-of-charge through UK Transplant.

1. Open eyelids and irrigate eyes with a sterile saline to remove debris, mucus and foreign matter. Clean face around the eyes, over eyelids, bridge of nose and eyebrows using alcohol wipes. Care should be taken not to touch the cornea with the alcohol wipes during this procedure.
2. Open the outer wrapper of a single-use instrument pack. Put on sterile gloves and place drapes and eye sheet over the donor.
3. Insert lid speculum and perform a peritomy using fine-toothed forceps and scissors, leaving a frill of conjunctiva around the limbus to protect the epithelial stem cell niche. Tenon's capsule is pushed back by entering each of the four quadrants with the scissors and performing a blunt dissection.
4. Isolate the lateral rectus muscle with a muscle hook, insert artery forceps between hook and sclera and clamp muscle. Remove muscle hook and cut muscle distal but close to the clamp. Isolate and cut each of the remaining rectus muscles in turn, cutting with the scissors between the muscle hook and the sclera. There is no particular need to cut the oblique muscles. Care must be taken not to rub the cornea against the speculum or instruments.
5. Gently lift the eye with the artery forceps. Insert the enucleation scissors from the medial side, and, keeping the scissors almost vertical, locate the optic nerve by moving the scissors gently from side to side. Still keeping the scissors almost vertical, cut the optic nerve while maintaining gently upward pressure on the eye with the artery forceps. This should ensure that a stump of optic nerve at least 5 mm long remains attached to the eye.
6. Once the optic nerve has been severed, gently raise the eye from the orbit, excising residual tissue with the enucleation scissors.
7. Carefully transfer the eye to a plastic eye stand, passing the stump of the optic nerve through the hole in the base of the stand. Secure the eye on the stand by placing a sterile 25G hypodermic needle through the side of the optic nerve. Place the eye stand and eye (cornea uppermost) on top of a cotton wool ball (or gauze swab) moistened with saline in a sterile pot (moist chamber). The eye must not be immersed in any liquid in the moist chamber.
8. Remove the speculum and repeat the procedure with the other eye.
9. Pack orbits with cotton wool and, with the aid of eye caps, restore the original appearance of the donor.
10. Clearly label the moist chambers with the date, donor's name, date of birth, hospital and whether LEFT or RIGHT eye.
11. For eyes being sent to one of the CTS Eye Banks, complete an NHSBT Ocular Tissue Donor Information form and Retrieval Site Risk Assessment form.. Pack the moist chambers and the blood sample into an NHSBT Human Tissue Transport box. Fill a plastic bag with melting ice (at least 1 kg) and place bag into the box. Place completed NHSBT Ocular Tissue Donor Information form and Retrieval Site Risk Assessment into the box. Contact the Duty Office at UK Transplant (Tel: 0117 975 7580) to report donor details and to arrange transport for the eyes.