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AGREEMENTS ON MINIMUM STANDARDS *

DONOR MEDICAL ASSESSMENT

PURPOSE

The purpose of these standards is to set out the principles of donor selection, describing the minimum information required for donor risk assessment, and the sources for information, which 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 activity that increases 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 autopsy is performed).

MICROBIOLOGICAL TESTING OF DONORS.

As a minimum sero-negativity for the following tests is required:

- HIV 1 and 2 antibody;
- HbsAg;
- HBc antibody;
- HCV antibody;
- Syphilis

Tests should be performed on a blood sample collected as soon as possible after death. The sample should be examined for haemolysis.

If the donor has received infusions within the last 48 hours, the volumes must be recorded and an algorithm applied to assess haemo-dilution.

Alternatively, an *ante mortem* blood sample taken before any transfusions or infusions, and up to 7 days before the donation, may be available for testing.

Heavy immunosuppression may invalidate serological antibody tests.

* By the EEBA Medical Special Interest Group: D. Ponzin (Chair), E. Trias, G. Thuret. Reviewed annually. Last revision: Jan 2008



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DONOR AGE AND *POST MORTEM* TIME

Provided that corneas are examined to exclude those with inadequate endothelium, no upper donor age limit needs to be set, but other age-related corneal changes must be taken into account. The lower age limit is less certain and will depend on surgical demand.

It is recommended that corneal preservation occurs as soon as possible after death. All time intervals for each donor (death to enucleation and preservation) shall be recorded.

CONTRAINDICATIONS TO THE USE OF DONOR OCULAR TISSUE FOR TRANSPLANTATION

1 INFECTIONS:

- 1.1 Rabies.
- 1.2 Acquired immunodeficiency syndrome (AIDS / HIV).
- 1.3 Active viral hepatitis (A, B, C).
- 1.4 Seropositivity: HIV, HbsAg, HCV, syphilis
- 1.5 Behaviour leading to risk of contracting HIV, hepatitis B or C¹.
- 1.6 Viral encephalitis or encephalitis of unknown origin, viral meningitis².
- 1.7 Congenital rubella.
- 1.8 Reyes syndrome.
- 1.9 Tuberculosis (active disease or within first six months of treatment.
- 1.10 Progressive multi-focal leucoencephalopathy.
- 1.11 Septicaemia².
- 1.12 Jaundice of unknown aetiology
- 1.13 HTLV 1 and 2 infection
- 1.14 Active malaria
- 1.15 Receipt of an organ transplant

2 UNKNOWN AETIOLOGY AND CNS DISORDERS:

- 2.1 Creutzfeldt-Jakob disease and the following risk groups:
 - Family history of CJD.
 - Recipients of dura mater or brain/spinal surgery before August 1992³
 - Recipients of human pituitary-derived hormones³.
- 2.2 Central nervous system diseases of unknown aetiology (e.g. multiple sclerosis, Alzheimer's disease, other dementias.)
- 2.3 Sub-acute sclerosing panencephalitis (slow infection caused by measles virus with symptoms resembling CJD)
- 2.4 Chronic fatigue syndrome
- 2.5 Death from unknown cause⁴

3 MALIGNANCIES and PREMALIGNANCIES:

- 3.1 Leukaemia.
- 3.2 Lymphoma.



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3.3 Myeloma.

4 EYE DISEASE AND OCULAR SURGERY:

- 4.1 Ocular inflammation (including known ocular involvement by systemic disease e.g. sarcoidosis, rheumatoid arthritis)
- 4.2 Congenital or acquired disorders of the eye, or previous ocular surgery that would prejudice graft outcome.
- 4.3 Retinoblastoma.
- 4.4 Malignant tumours of the anterior segment.
- 4.5 Receipt of a corneal, scleral or limbal graft

USE OF PRESERVED SCLERAL TISSUE

Donor medical assessment is the same as for corneas.

USE OF LIMBAL TISSUES FOR KERATO-LIMBAL-ALLOGRAFTS

Donor medical assessment is the same as for corneas.

Malignancies represent additional contraindications because the limbus is vascularised.

NOTES:

¹ 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)
 - tattooing, acupuncture, ear or body piercing
 - imprisonment

² 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. Additional microbiological testing is required.

³ Increased risk of CJD transmission.

⁴ 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.