Clinical Process Instruction Manual

General Tissue Donation Criteria and Contraindications Process Instruction

Policy:

General criteria and contraindications are used to determine the suitability for tissue donation including accepting or excluding a tissue donor. It is the responsibility of Health Canada/Canadian Standards Association (HC/CSA), American Association of Tissue Banking (AATB), EBAA (Eye Bank Association of America), and the Ontario Tissue Banks to specify the exclusion criteria for tissue donation. All referrals and potential donors must be screened as per the exclusion criteria of HC/CSA, AATB and the Tissue Banks prior to making an offer and/or recovering the tissue. See Appendices 1 to 14. Potential donors should be evaluated individually and based on all gathered and readily available information. Sources include, information the Tissue Coordinator (TC) receives from the Donor Referral (hospital, paramedic, hospice, coroner, community) and *Medical & Social History Questionnaire* (MSHx) or relevant *Donor Risk Assessment Interview(s)* (DRAI) as well as information the Tissue Recovery Coordinator (TRC) obtains when completing the chart review and donor physical assessment.

Process:

1. When a referral is made to Trillium Gift of Life Network (TGLN), the TC must screen the potential donor to determine medical suitability for ocular and tissue donation.

2. The patient's health information must be obtained from the hospital chart via the Health Care Professional (HCP) on the phone and recorded in iTransplant. Required fields and entry format in DMS are outlined in *iTransplant: Tissue Exclusive Manual.*

3. The information needed to determine suitability includes but is not limited to:

   - patient's age
   - cause of death
   - current course of events and past medical history
   - any positive contra-indicators
   - white blood cell counts, temperatures
   - culture results (blood, urine, sputum)
   - diagnostic test results (cxr, ultrasound)
   - medications and antibiotics given

4. Once the patient's health information has been obtained, and prior to consent, the TC must review the exclusion criteria, as they apply to each tissue bank, to determine if the patient is suitable for tissue donation and if an approach to the next-of-kin (NOK) is reasonable.

5. Once the consent and MSHx or relevant DRAI have been completed, the TC must once again review the tissue bank exclusion criteria to determine suitability based on new information gathered from the MSHx or UDRAI and to determine TC will accept the donor on behalf of the applicable Tissue Bank(s). The only exception is ocular donation, where the TC will contact The Eye Bank of Canada (EBC) directly to offer the ocular tissue and record whether or not EBC accepts or defers the tissue. For all other Tissue Banks, once suitability is determined, the TC will inform the Tissue Bank(s) for which the tissue has been accepted.

6. If an Ocular Tissue Recovery Coordinator (OTRC) or Multi Tissue Recovery Coordinator (MTRC) is dispatched to recover the tissue, the OTRC and/or MTRC must complete a chart review and physical assessment to confirm the medical suitability of the potential donor prior to recovery.

7. At any point, the TC/TRC/MTRC may contact the Medical Director-Tissue to review the suitability of the donor.

8. Post recovery assessment of the tissue suitability is the responsibility of the Tissue Banks and their respective Medical Directors.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Donor Medical and Social History Questionnaire	CSF-9-14	PRC	PRC	16 years
Eye-Only Donor Risk Assessment Interview (Donor > 10 years old)	CSF-9-214	PRC	PRC	16 years
Eye-Only Donor Risk Assessment Interview (Child Donor ≤ 10 years old)	CSF-9-215	PRC	PRC	16 years

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Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Eye-Only Donor Risk Assessment Interview Birth Mother	CSF-9-216	PRC	PRC	16 years
Donor Risk Assessment Interview (Donor > 10 years old)	CSF-9-261	PRC	PRC	16 years
Donor Risk Assessment Interview (Child Donor ≤ 10 years old)	CSF-9-262	PRC	PRC	16 years
Donor Risk Assessment Interview Birth Mother	CSF-9-263	PRC	PRC	16 years

References:

- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D4.000, D4.100
- *Physical Examination for Tissue Process Instruction, CPI 9-467*
- *Eye Tissue Recovery Preparation and Responsibilities Process Instruction, CPI 9-465*
- *Hemodilution Calculation Process Instruction, CPI 9-210*

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Appendix 1: CSA Standards - General Requirements

13.1.5

The risk of emerging diseases/pathogens shall be assessed to determine if additional contraindication criteria or screening criteria, or both, are necessary.

Notes:

1) *This includes an infectious disease that has newly appeared in a population or that has been known for some time but is rapidly increasing in incidence or geographic range.*
2) *Governmental health ministries, departments, and other agencies issue alerts/notices for guidance, as applicable.*
3) *Establishments may establish/update/modify SOPs so that donor screening criteria is more stringent than current federal regulation or the CSA Group standards.*

13.1.2

Each establishment shall establish guidelines for the evaluation of general or specific contraindication criteria.

13.1.3

A donor shall be excluded if any of the following contraindications apply:

a) persons whose probable cause of death cannot be adequately determined by the medical director of the source establishment and there is likelihood of other exclusionary criteria;
b) persons who died from neurological disease of an unestablished etiology;
c) persons with prion-related disease;
d) recipients of human growth hormone within the following time frames:
   i) prior to 1986, if the treatment took place in Canada or the US; or
   ii) if the treatment took place in a country other than Canada or the US, anytime that human-derived pituitary growth hormone was available for therapeutic use in that country;

   Note: *This Item refers to growth hormone extracted from human pituitary glands, used for therapeutic purposes prior to 1986. The human-derived product was removed from the market in Canada and the US and replaced with a recombinant manufactured product, due to a possible link between the human-derived product and Creutzfeldt-Jacob disease.*
e) recipients of dura mater;
f) persons with active encephalitis or meningitis of infectious or unknown etiology;
g) persons with a history of dementia or degenerative neurologic disorders of viral or unknown etiology;
h) persons with rabies or persons who, within the past six months, were bitten by an animal and treated as if the animal was rabid;
i) persons with a history of infection with HIV, clinically active HCV, or clinically active HBV;
j) persons at higher risk for HIV, HBV, or HCV infections as specified in Annex E; and
k) persons with infections that would pose a significant risk to the recipient if transmitted.

Notes:

1) *Regarding Item k), it is a matter of clinical judgement to determine the significance/level of risk depending on the clinical history, type of transplant, etc.*
2) *Items a) and b) do not apply to living donors.*

13.1.4

Exceptional distribution of cells, tissues, or organs from donors to whom any of the contraindication criteria in Clause 13.1.3 or Annex E apply shall be in accordance with Clause 18.4.

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General Tissue Donation Criteria and Contraindications Process Instruction

Appendix 2: CSA Standards - Tissues for Transplantation

13.1.5

The following criteria, based on review and clinical interpretation by the medical director, should be considered as potential contraindications or exclusion criteria for donation of cardiovascular tissue:

a) bacterial endocarditis;
b) rheumatic fever;
c) semilunar valvular disease;
d) cardiomyopathy of viral or idiopathic etiology;
e) Chagas' disease; and
f) for mitral valve donation, history of mitral valve disease, including mitral valve prolapse.

In addition to the contraindications or exclusion criteria listed in Clause 13.1.3 of CAN/CSA-Z900.1, a donor shall be excluded if any of the following contraindications apply:

a) persons with active malaria;
b) persons with active tuberculosis;
c) persons with HTLV-I or HTLV-II;
d) persons with a biological parent or blood-related sibling with a confirmed case of Creutzfeldt-Jakob disease (CJD);
e) persons with current diagnosis of lymphoma or leukemia;
f) persons with active syphilis; and
g) persons with history of active or past Ebola infection.

Notes:

1) *A lack of knowledge of CJD in response to Item d) is a presumed negative answer.*
2) *Other malignancies in addition to those stated in Item e) may be included upon the medical director's review and recommendation.*

13.1.3

Each tissue bank, donation agency, or transplant service shall establish guidelines for evaluation of other general or tissue-specific infections and contraindications. A clinical decision shall be necessary in the following situations:

a) untreated systemic infection;
b) jaundice;
c) systemic immunosuppression;
d) autoimmune diseases;
e) trauma to the potential retrieval site;
f) septicemia;
g) leprosy; and
h) systemic mycosis.

13.1.4

The following criteria, based on review and clinical interpretation by the medical director, should be considered as potential contraindications or exclusion criteria for donation of musculoskeletal and bone tissue:

a) rheumatoid arthritis;
b) systemic lupus erythematosus;
c) polyarteritis nodosa;
d) sarcoidosis; and
e) clinically significant metabolic bone disease.

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General Tissue Donation Criteria and Contraindications Process Instruction

Appendix 3: CSA Standards - Ocular Tissues for Transplantation

13 Donor screening

13.1 Contraindications or exclusion criteria

13.1.1 General

In addition to the requirements specified in Clause 13.1 of CAN/CSA-Z900.1, the requirements specified in Clauses 13.1.2 to 13.1.6 of this Standard shall apply.

13.1.2 Use of contraindicated ocular tissues

The contraindications associated with specific uses of ocular tissues are outlined in Clauses 13.1.3 to 13.1.6. Ocular tissues from donors excluded under the contraindications listed in Clause 13.1.3 shall not be offered for surgical purposes. Ocular tissues may be offered for surgical purposes under the conditions and for the purposes specifically permitted in Clauses 13.1.4 to 13.1.6.

Notes:

1) *The use of contraindicated tissues represents a potential health threat for the recipient(s) of that tissue and can pose a risk to the success of the surgery.*
2) *Clauses 13.1.4 to 13.1.6 include permissible uses for certain tissues from donors that are otherwise excluded.*

13.1.3 Exclusion criteria for ocular tissues

A donor for ocular tissues shall be excluded if any of the following contraindications apply:

Note: *The following are in addition to the contraindications specified in Clause 13.1.3 of CAN/CSA-Z900.1.*

a) persons with congenital rubella;
b) persons who have had Reye's syndrome within the previous three months;
c) persons with active septicemia (bacteremia, fungemia, viremia);
d) persons with active bacterial or fungal endocarditis;
e) persons with active leukemia;
f) persons with myeloma or active lymphoma;
g) persons with Down's Syndrome, except in the case of scleral tissue, posterior lamellar keratoplasty, and keratolimbal or conjunctival grafts;
h) persons with congenital or acquired disorders of the eye that would preclude a successful outcome for the intended use (e.g., keratoconus, keratoglobus, or a central corneal scar for an intended penetrating keratoplasty);
i) persons with a history or signs of anterior segment surgery or other corneal disorders;
j) persons with a history of active or past Ebola infection;
k) persons with a history of melanoma with known metastatic disease, with the exception of irradiated ocular tissue; and
l) persons with intrinsic eye disease that would preclude good success of the transplant or would have a risk of transmitting disease.

Notes:

1) *If a person with an intrinsic eye disease has only one eye that is affected, the unaffected eye may be considered for use.*
2) *Examples of intrinsic eye disease include, but are not limited to,*
   a) *malignant tumours of the eye whether of primary or metastatic origin (e.g., retinoblastoma, melanoma, adenocarcinoma);*
   b) *active ocular or intraocular inflammation (conjunctivitis, keratitis, scleritis, iritis, uveitis, vitreitis, choroiditis, retinitis); and*
   c) *history of past herpes simplex virus corneal infection.*

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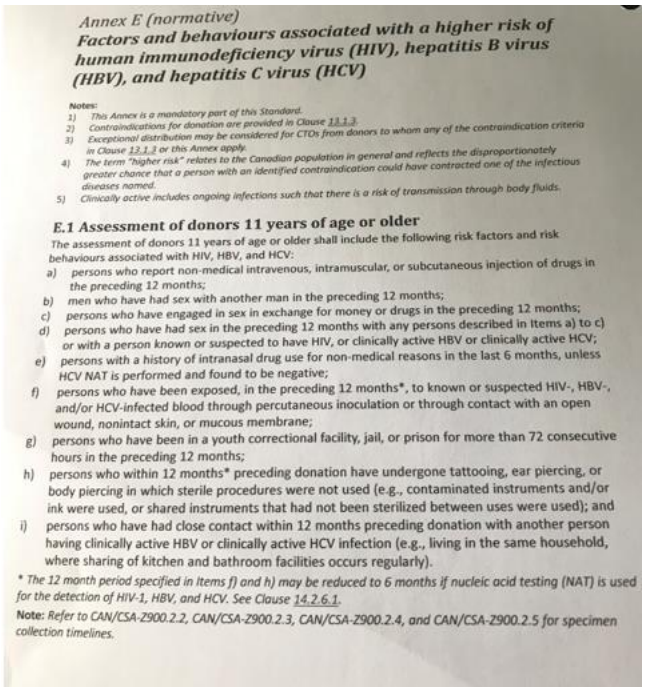
Appendix 4: CSA Standards – Annex E



Annex E (normative)

Factors and behaviours associated with a higher risk of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV)

Notes:

1) *This Annex is a mandatory part of this Standard.*
2) *Contraindications for donation are provided in Clause 13.1.3.*
3) *Exceptional distribution may be considered for CTOs from donors to whom any of the contraindication criteria in Clause 13.1.3 or this Annex apply.*
4) *The term "higher risk" relates to the Canadian population in general and reflects the disproportionately greater chance that a person with an identified contraindication could have contracted one of the infectious diseases named.*
5) *Clinically active includes ongoing infections such that there is a risk of transmission through body fluids.*

E.1 Assessment of donors 11 years of age or older

The assessment of donors 11 years of age or older shall include the following risk factors and risk behaviours associated with HIV, HBV, and HCV:

a) persons who report non-medical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 12 months;
b) men who have had sex with another man in the preceding 12 months;
c) persons who have engaged in sex in exchange for money or drugs in the preceding 12 months;
d) persons who have had sex in the preceding 12 months with any persons described in Items a) to c) or with a person known or suspected to have HIV, or clinically active HBV or clinically active HCV;
e) persons with a history of intranasal drug use for non-medical reasons in the last 6 months, unless HCV NAT is performed and found to be negative;
f) persons who have been exposed, in the preceding 12 months*, to known or suspected HIV-, HBV-, and/or HCV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane;
g) persons who have been in a youth correctional facility, jail, or prison for more than 72 consecutive hours in the preceding 12 months;
h) persons who within 12 months* preceding donation have undergone tattooing, ear piercing, or body piercing in which sterile procedures were not used (e.g., contaminated instruments and/or ink were used, or shared instruments that had not been sterilized between uses were used); and
i) persons who have had close contact within 12 months preceding donation with another person having clinically active HBV or clinically active HCV infection (e.g., living in the same household, where sharing of kitchen and bathroom facilities occurs regularly).

** The 12 month period specified in Items f) and h) may be reduced to 6 months if nucleic acid testing (NAT) is used for the detection of HIV-1, HBV, and HCV. See Clause 14.2.6.1.*

Note: *Refer to CAN/CSA-Z900.2.2, CAN/CSA-Z900.2.3, CAN/CSA-Z900.2.4, and CAN/CSA-Z900.2.5 for specimen collection timelines.*

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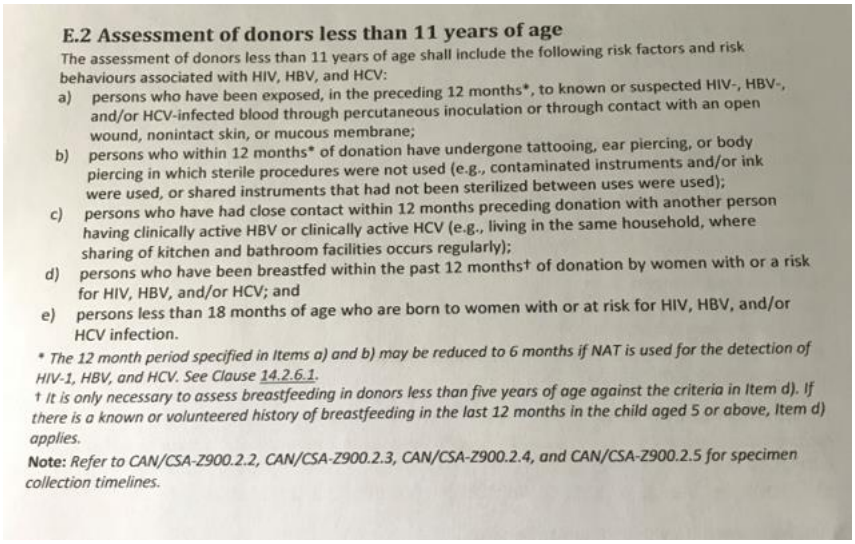

E.2 Assessment of donors less than 11 years of age

The assessment of donors less than 11 years of age shall include the following risk factors and risk behaviours associated with HIV, HBV, and HCV:

a) persons who have been exposed, in the preceding 12 months*, to known or suspected HIV-, HBV-, and/or HCV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane;

b) persons who within 12 months* of donation have undergone tattooing, ear piercing, or body piercing in which sterile procedures were not used (e.g., contaminated instruments and/or ink were used, or shared instruments that had not been sterilized between uses were used);

c) persons who have had close contact within 12 months preceding donation with another person having clinically active HBV or clinically active HCV (e.g., living in the same household, where sharing of kitchen and bathroom facilities occurs regularly);

d) persons who have been breastfed within the past 12 months† of donation by women with or a risk for HIV, HBV, and/or HCV; and

e) persons less than 18 months of age who are born to women with or at risk for HIV, HBV, and/or HCV infection.

** The 12 month period specified in Items a) and b) may be reduced to 6 months if NAT is used for the detection of HIV-1, HBV, and HCV. See Clause 14.2.6.1.*

† It is only necessary to assess breastfeeding in donors less than five years of age against the criteria in Item d). If there is a known or volunteered history of breastfeeding in the last 12 months in the child aged 5 or above, Item d) applies.

Note: *Refer to CAN/CSA-Z900.2.2, CAN/CSA-Z900.2.3, CAN/CSA-Z900.2.4, and CAN/CSA-Z900.2.5 for specimen collection timelines.*

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Appendix 5: EBAA Medical Standards – D1.110

D1.110 EBAA Contraindications to Transplant

Tissues from persons with the following are potentially health threatening for the recipient(s) or pose a risk to the success of the surgery and shall not be offered for surgical purposes:

A. All Ocular Donors

1. death of unknown cause and there is likelihood of other exclusionary criteria;
2. congenital rubella;
3. Reye syndrome within the past three months;
4. Active viral encephalitis of unknown origin or progressive encephalopathy (e.g., subacute sclerosing panencephalitis, progressive multifocal leukoencephalopathy, etc.);
5. active bacterial or viral meningitis;
6. active bacterial or fungal endocarditis;
7. suspected rabies and persons who, within the past six months, were bitten by an animal suspected to be infected with rabies;
8. Down Syndrome - exclusively for penetrating keratoplasty or anterior lamellar keratoplasty;
9. intrinsic eye disease;
    a. retinoblastoma;
    b. malignant tumors of the anterior ocular segment or known adenocarcinoma in the eye of primary or metastatic origin;
    c. active ocular or intraocular inflammation: conjunctivitis, keratitis, scleritis, iritis, uveitis, vitreitis, choroiditis, retinitis; or

d. congenital or acquired disorders of the eye that would preclude a successful outcome for the intended use, e.g., a central donor corneal scar for an intended penetrating keratoplasty, keratoconus, and keratoglobus;

10. active leukemias;
11. active disseminated lymphomas;
12. Parkinson, amyotrophic lateral sclerosis, multiple sclerosis, and Alzheimer disease;
13. Creutzfeldt-Jakob disease (CJD), variant Creutzfeldt-Jakob Disease (vCJD), or family member with CJD;
14. history of Ebola Virus Disease (EVD);
15. history of melanoma with known metastatic disease*

B. Donors for Penetrating Keratoplasty Procedures

1. Prior intraocular or anterior segment surgery
   a. Refractive corneal procedures, e.g., radial keratotomy, lamellar inserts, etc.
   b. Laser photoablation surgery (these corneas may be used for tectonic grafting and posterior lamellar procedures).
   c. Corneas from patients with anterior segment (e.g., cataract, intraocular lens, glaucoma filtration) surgery may be used if screened by specular microscopy and they meet the eye bank's endothelial standards.
2. Pterygia or other superficial disorders of the conjunctiva or corneal surface involving the central optical area of the corneal button.

C. Donors for Anterior Lamellar Keratoplasty Procedures, Tectonic Grafts, and Patch Grafts such as for glaucoma drainage devices (non-vascular ocular tissue excluding sclera).

Criteria are the same as listed for penetrating keratoplasty, except that tissue with local eye disease affecting the corneal endothelium or previous ocular surgery that does not compromise the corneal stroma, (e.g., donors with a history of endothelial dystrophy or iritis are acceptable).

D. Donors for Epikeratoplasty Procedures

Criteria are the same as listed for penetrating keratoplasty, except that tissues with local eye disease affecting the corneal endothelium, (e.g., donors with a history of endothelial

dystrophy or iritis) are acceptable. Death to preservation time may be extended.

E. Donors for Endothelial Keratoplasty Procedures

Criteria are the same as listed for penetrating keratoplasty, except that tissue with non-infectious anterior pathology that does not affect the posterior stroma and endothelium is acceptable. Surgeons must be notified of any prior pathology prior to placing tissue for transplant.

F. Scleral Tissue Donors

Criteria are the same as listed for penetrating keratoplasty, except that tissue with non-infectious local eye disease or refractive surgery affecting the cornea is acceptable for use. Death to preservation time may be extended. Donors with history of melanoma (with or without metastasis) or solid, cancerous, non-melanoma tumor with metastasis are contraindicated (unless the donated tissue is irradiated).

G. Donors for Keratolimbal Allograft Procedures (vascular ocular tissue)

Conjunctival and limbal area must be intact and free of evidence of disease (e.g. pterygium, neovascularization). Structural condition of central stroma and endothelium is inconsequential. Limbal tissue and peripheral corneal tissue are vascular tissue. Donors with a history of melanoma (with or without metastasis) or a solid cancerous, non-melanoma tumor with metastasis are contraindicated.

* irradiated tissue is excluded from these contraindications

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Appendix 6: Sample Eye Bank of Canada Ontario Division (EBCOD) Exclusion Criteria

EYE BANK OF CANADA Exclusion Criteria for Transplant *alphabetical order* NB: Conditions with *** noted will have RT potential only
Active Lyme disease***
alzheimer's/dementia ***
amyloidosis
amyotrophic lateral sclerosis (ALS) ***
bowel perforation (at TOD) ***
carbapenemase-producing Enterobacteriaceae (CPE)***
carbapenem-resistant Enterobacteriaceae (CRE)***
central pontine myelinolysis
crack and cocaine (current or in last year) ***
creutzfeldt–Jakob disease (CJD)
crystal meth use (current or in past year) ***
current clostridium Difficile Colitis (C. diff)***
current ESBL***
current incarceration ***
current MRSA/VRE (treated and culture-negative acceptable)***
current urosepsis ***
hepatitis B and C
herpes encephalophathy
HIV/AIDS
homelessness (current) ***
irititis ***
Non-Prescription IV drug use (current or in past year)
leukemia ***
lymphoma ***
male-to-male sexually active in the past 5 years ***
melanoma ***
multiple myeloma ***
multiple sclerosis (MS) ***
myelinoclastic disorders ***
positive sputum cultures for H-influenzae ***
progressive multifocal leukoencephalopathy (PML)
rabies
sepsis (documented or query of sepsis) ***
shingles (on the face)
syphilitic myelopathy
vomiting feces ***
Zika infection (active in the past 6 months) or travel to an area with Zika endemic/exposure in the past 21 da

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Appendix 7: Sample Hospital for Sick Children Criteria for Heart Valves Exclusion Criteria

Hospital for Sick Children Exclusion Criteria for Heart Valves

Any 'Yes' to the following questions means the donor is medically unsuitable

General	Yes
Time Requirements	
Not refrigerated within 12 hours of death and >15 hours from time last seen alive/time of death	
>24 hours from time last seen alive/time of death	
Death from an unknown cause	
Unwitnessed death with no history or circumstances or recent symptoms or laboratory findings to indicate a probable cause of death. Acceptable if an autopsy is planned and there are no other exclusion criteria.	
Age	
<36 weeks or >60 years Note: Suitable donors with ages between 36 weeks to 60 years (inclusive)	
Weight	
< 6 lbs or 2.73 kg	
Historian	
Individual providing the donor history appears unreliable and/or unable to answer key questions and there is no other family member or family physician to provide the necessary medical and social history	
Disease Screening Exclusionary Criteria	**Yes**
Infections	
Evidence of active infection at the time of donation including, but not limited to: a) Viral infections (e.g. HIV, viral hepatitis, HTLV I/II, WNV, subacute sclerosing panencephalitis, progressive multifocal leukoencephalopathy, rabies, rubella, RSV) b) Parasitic diseases (Chagas' disease, toxoplasmosis) c) Fungal infections (e.g. systemic mycosis) d) Bacterial infections with known or suspected sepsis (e.g. pyelonephritis, pneumonia or consolidation in chest X-ray), osteomyelitis, bacterial endocarditis, cellulitis, syphilis, tuberculosis, and leprosy (Hansen's disease). Acceptable if the patient has completed the prescribed course of antimicrobial therapy and is now asymptomatic. e) Diarrhea (infectious or unexplained cause) f) Prion disease (e.g. Creutzfeldt-Jakob disease)	
Cultures	
Positive blood or spinal fluid cultures unless the patient has completed a prescribed course of antimicrobial therapy and follow up cultures are negative.	
Malignancies	
Malignancy with potential for metastatic disease Acceptable: Primary brain tumors (benign or malignant), basal cell carcinoma and squamous cell carcinoma of skin, in-situ cervical cancer	
Additional Adverse Conditions that are not acceptable	
1) Any autoimmune disease that can potentially affect the heart (e.g. systemic lupus erythematosus, polyarteritis nodosa)	
2) History of coronary artery bypass grafting	
3) Viral or idiopathic cardiomyopathy	
4) History of semilunar valve disease or damage (including that caused by bacterial endocarditis)	
5) Granulomatous disease (e.g. sarcoidosis)	

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Appendix 8: Sample Mount Sinai Allograft Technologies (Bone) Exclusion Criteria

MOUNT SINAI
Mount Sinai Allograft Technologies
600 University Avenue, Toronto, ON M5G 1X5
Phone: 416-586-8870/Fax: 416-586-4458

Accredited with the American Association of Tissue Banks Since 1990

Alphabetical Exclusion List for Bone & Tissue Donation

A

Active Disseminated Lymphomas(incl. Hodgkins, non-Hodgkins and Sezary syndrome)
Active infection (A combination of 2 of the following 3 factors: Temperature greater than 39 degrees, WBC greater than 13 and/or on antibiotics)
Addison's Disease
Alzheimer's Disease
Amyloidosis
Amyotrophic Lateral Sclerosis (ALS)
Anorexia/Malnourishment
Anemia (not due to acute hemorrhage)
Aspergillosis Infection
Aspiration
Autoimmune Diseases
Autoimmune Hemolytic Anemia
Autoimmune Thrombocytopenic Purpura

B

Billary Cirrhosis – primary
Blue or purple spots consistent with Kaposi's sarcoma (blue/purple [gray/black] spots/lesions)
Bowel - preforation
Brucellosis Infection (systemic)
Bullous Pemphigus

C

Carcinoma
Cause of Death - Cardiac Arrest (with no past cardiac history or autopsy planned)
Cause of Death - Respiratory Arrest (with no past medical history and autopsy planned)
Cause of Death – Unknown
Cause of death-Neurological (no known etiology)
Chemotherapy for cancer
Chlamydia
Chronic Thyroiditis (Hashimoto's disease)
Clinically Active Hepatitis C
Coccidioidomycosis Infection
Consent Form for Donation - Lack of
Consent Form for Donation - Not Completed
Consent Form for Donation - Not Signed
Contact (intimate) with Individual Having a History of High Risk Behavour
Contact (intimate) with Individual Having a Relevant Communicable Disease Agent or Disease (RCDAD)
Contact (intimate) with Recipient of Xenotransplant
Contact with or exposed to individual(s) with SARS or Travel to Area Suspected of SARS
Corneal Tissue Recipient
Corneal scarring consistent with vaccinial keratitis (abnormal ocular finding, scarring)
Crack (Crack Cocaine) Use
Creutzfeldt-Jakob disease (CJD)
Crohn's Disease
Cushing's Syndrome (glucocorticosteroid excess)

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Appendix 9: Sample Sunnybrook Health Sciences Centre Tissue Exclusion Criteria for Skin Donors

Sunnybrook HEALTH SCIENCES CENTRE 2075 Bayview Avenue Toronto, ON M4N 3M5	Department of LMMD Division of Transfusion Medicine and Tissue Bank **Tissue Bank**	TBK-5.10.1.1.2 Version: 9 Page 1 of 4 Effective: 2019/08/26 E-Authorized by: Transfusion Medicine Specialist

Sunnybrook Health Sciences Centre Tissue Exclusion Criteria for Skin Donors

General
Time Exclusions
Not refrigerated within 12 hours of death and >15 hours from time last seen alive/time of death
>24 hours from time last seen alive/time of death
Specimen Collection Exclusionary Time Limits
Pre-mortem specimens collected more than 7 days before death Post-mortem specimens collected more than 15 hrs after death
Palliative
>2 days palliative care or no diagnostic testing for 2 days due to withdrawal of care
Death from an unknown cause
Unwitnessed death with no history or recent symptoms or laboratory findings to indicate a probable cause of death. Presumed cardiac death must have evidence of coronary artery disease (ST elevation on ECG, Ventricular Tachycardia or Fibrillation, occlusion on angiogram, etc). Acceptable if an autopsy is planned and there are no other exclusion criteria. Cause of death on the death certificate cannot be used at face value unless there is medical evidence to justify the diagnosis.
Age
<18 or >75 yrs
Weight/height
<110lbs, < 5ft, BMI <20 or >40
Historian
Individual providing the donor history appears unreliable and/or unable to answer questions and there is no other family member or family physician to provide the necessary medical and social history
Disease Screening Exclusionary Criteria
Infections
Evidence of active infection at the time of donation including, but not limited to: a) viral infections e.g. HIV, viral hepatitis, HTLV I/II, WNV, subacute sclerosing panencephalitis, progressive multifocal leukoencephalopathy, rabies, b) parasitic diseases e.g. T. Cruzi (Chagas disease), c) fungal infections e.g. systemic mycosis d) bacterial infections with known or suspected sepsis, (e.g. bladder infection, pyelonephritis pneumonia or consolidation in chest X-ray of the lungs), cellulitis, sacral ulcers, diabetic foot ulcers, syphilis, tuberculosis, leprosy (Hansen's disease) e) diarrhea (infectious or unexplained cause) f) prion disease (transmissible spongiform encephalopathy) e.g. vCJD, Acceptable if the patient has completed the prescribed course of antimicrobial therapy and is now asymptomatic (only for bacterial infections).
Cultures
Positive blood or spinal fluid cultures unless the patient has completed a prescribed course of antimicrobial therapy and follow up cultures are negative. Positive sputum cultures will be assessed based on the type of organism, antibiotics administered, chest-x-ray results, and timing of positive culture to time of death.

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Appendix 10: Sample Lake Superior Centre for Regenerative Medicine (RegenMed) Bone Tissue Bank Donor Suitability Guide

Donor Suitability Guide

Refer to DSC-F-024 Approved Acronyms and Meanings for a list of acronyms used in this document.

This Donor Suitability Guide is provided to assist tissue donation screeners, coordinators, staff and Medical Directors of RegenMed and Recovery Partners in determining suitability of potential donors for recovery. This guide is subject to change and will be periodically modified to adapt to emerging infectious diseases.

Each donor shall be evaluated according to established criteria. Donor suitability criteria are established by RegenMed Medical Director(s) in accordance with applicable standards and regulations. The suitability of each donor shall be determined by the Medical Director or licensed physician designee upon review of all records described in DSC-10-018 Medical Director Donor Suitability Review. Donor suitability shall be based on medical and social history, clinical status, physical examination, laboratory tests, plasma dilution assessment (if required) and autopsy (if performed). Suitability criteria that have been established by Health Canada and the American Association of Tissue Banks (AATB) are accepted and included in this guide.

Prior to recovery of tissue from a potential deceased donor, a physical assessment shall be performed by a responsible person. This shall be a recent ante-mortem or post-mortem physical assessment to identify evidence of high risk behaviour and signs of HIV infection or hepatitis infection, other viral or bacterial infections, and/or trauma to the potential recovery sites.

If any of the following signs are observed or noted in any available record and are deemed to be an indication of these risks, the tissue shall be rejected.

1. Physical evidence for risk of sexually transmitted diseases such as genital ulcerative disease, herpes simplex, chancroid [**genital lesions**];
2. Physical evidence for risk of, or evidence of, syphilis [**genital lesions, rash, skin lesion** (non-genital)];
3. For a male donor, physical evidence consistent with anal intercourse including perianal condyloma [**insertion trauma, perianal lesions**];
4. Physical evidence of non-medical percutaneous drug use such as needle tracks [and/or **non-medical injection sites**] including tattoos which may be covering needle tracks;
5. Disseminated lymphadenopathy [**enlarged lymph nodes**];
6. Unexplained oral thrush [**white spots in the mouth**];
7. Blue or purple spots consistent with Kaposi's sarcoma [**blue/purple (gray/black) spots/lesions**];
8. Physical evidence of recent tattooing, ear piercing, or body piercing [**tattoo/piercings require description**];
9. Unexplained jaundice, icterus or hepatomegaly [**enlarged liver** may not be apparent in a Physical Assessment unless an autopsy is performed];
10. Physical evidence of sepsis, such as unexplained generalized rash/generalized petechiae or fever;
11. Large scab consistent with recent smallpox immunization;
12. Eczema vaccinatum [**lesion, scab**];
13. Generalized vesicular rash, generalized vaccinia;
14. Severely necrotic lesion consistent with vaccinia necrosum;
15. Corneal scarring consistent with vaccinial keratitis [**abnormal ocular finding**]; and/or
16. Trauma to the retrieval site(s).