Donor Medical & Social History Questionnaire: Description and Rationale

Purpose of the Questionnaire

Information obtained from the *Donor Medical and Social History Questionnaire* provides valuable information regarding donor suitability for the purposes of exceptional distribution, and factors into the decision about whether to accept organs and/or tissue for transplantation. Donor history is critical to identifying the risk versus benefit for a potential transplant recipient. The final decision regarding eligibility to donate is made by the tissue bank medical director and/or the transplant physician(s). Consultation with TGLN's Chief Medical Officer may provide guidance on whether exceptional distribution protocols are necessary.

Approach

The interviewer's comfort level with the questions in the *Donor Medical and Social History Questionnaire* (MSHx) impacts the tone of the interview. Comfort and familiarity with the questions is beneficial and helps to place everyone at ease.

One option for starting the interview is to ask the interviewee if she/he has ever donated blood, and to draw similarities between the questions used in the process. The interviewer should explain the purpose of the MSHx and explain that the purpose of the questionnaire is to learn if the potential donor had any previous illnesses or conditions that might prevent donation of certain organs and tissues, and to prevent the transmission of any disease through transplantation.

It is important to ask all the same questions in the same way. Do not apologize for having to ask the questions. Although an apology is well meant, it may imply the interviewer does not believe questions are appropriate to the situation or that the interviewer is not comfortable with the questions or answers. It may discourage the interviewee from answering the questions to the fullest extent of their knowledge.

Responses of 'yes' or 'unknown' to questions may require further investigation. It is the responsibility of the interviewer to exercise clinical judgement and critical thinking to prompt interviewee for elaboration on responses. Information gathered from the interviewee could provide insight on severity and treatment of condition identified, or could provide direction to a source where more information could be discovered about the condition, such as past medical records.

Responsibilities of the Person Conducting Interview & Completing Form

Ethical Considerations

The medical and social history of the donor directly affects the future health of transplant recipients. The questions are an important way to ensure recipients receive the best possible chance for future good health and quality of life. Further, families donate organs and tissue with the belief that another person will benefit. To honour the donor families' intentions and provide the best outcome for all involved, interviewers must *consistently ask ALL questions* in the questionnaire without fail. Failure to do so deviates from the requirements of the Health Canada Regulations and CSA Standards.

Legal Considerations

The existence of standards for screening of human tissue and organ donation set expectations for practice. The MSHx is in accordance to Health Canada's *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* and provides the interviewer with a tool to consistently meet its requirements. Document complete responses to all questions and clarify any answers that are unclear. Consistency in asking all questions establishes a standard of practice that acknowledges the responsibility to both donor families and transplant recipients.

Questions & Rationale

General Health Information		
	Question	**Rationale**
1	What is the name and phone number of his/her family physician?	The donor's family physician may be contacted in the event that more detailed information is necessary.
2	Was he/she born outside of Canada?	Birth and/or extended residence in certain geographical regions during specified time periods predisposes donors to certain infectious disease risks. E.g., Some of these risks could include regions of Europe 1980-1996 (CJD risk)
3	Has he/she been seen by a physician or been hospitalized (including psychiatric or long-term facility)?	Provides general health information for medical evaluation. Name of physician and facility aid in gathering more information if required.
4	Did he/she have any past major illness or surgical procedures?	Encourages interviewees to recall any significant medical problems.
5	Did he/she have any history of cancer or malignancy including: • skin cancer, • myeloma, • leukemia, or • lymphoma?	Malignancies: i.e., a tumor, growth or mass that has not been documented as being benign by a physician (exceptions: cutaneous basal cell or squamous cell carcinoma that has been treated) OR history of malignancy (except for cutaneous basal cell or squamous cell carcinoma that has been treated) Certain types of cancer may not exclude donation, such as basal cell cancer of the skin, non-metastatic primary brain tumours or in-situ cervix carcinoma. Transplant physicians and/or the medical director shall evaluate the type of malignancy, clinical course and cancer treatment prior to acceptance as a donor.
6	Did he/she suffer from any condition that may restrict his/her activities of daily living, such as: • shortness of breath or • chest pains?	General health question to assess potentially undiagnosed symptoms for lung and cardiac assessment.
7	Did he/she have any physical limitations requiring assistive devices, such as a: • cane • walker, or • wheelchair?	Overall bone quality decreases in those with decreased weight bearing ability or mobility restrictions over a significant period of time.
8	Was he/she taking any medication prior to hospital admission?	The use of certain medications may indicate a disease process for further investigation

9	Did he/she have any allergies?	Provides general health information and may reveal a history of asthma or other potential life-threatening conditions that required treatment.
10	Did he/she have extensive exposure to toxic substances, such as: • pesticides, • lead, • mercury, • asbestos, or • black mould?	Exposure to certain chemicals at high levels or over long periods of time may result in a residual amount harboured in the tissues. It is important to determine if the potential donor routinely worked around potentially toxic chemicals.
11	Did he/she have any history of diabetes (including gestational)?	Juvenile onset, insulin-dependent (Type-1) diabetes is thought to be an autoimmune process. Adult onset diabetes is generally treated with diet and/or oral medication. The use of bovine (cow derived) insulin manufactured in the UK after 1980 carries the risk of transmission of Creutzfeldt-Jakob Disease (CJD). Knowledge of the type of diabetes (Juvenile-onset-Type l vs. Adult onset-Type ll) duration and treatment(s) used will help evaluate suitability for both organ and tissue donation.
12	Did he/she have any history of kidney related disease, such as: • kidney stones, • infections, or • dialysis?	Evaluates medical suitability of kidneys. Kidney failure causes metabolic changes that make bone donation unacceptable in patients with chronic renal failure. Pyelonephritis, a scarring infection of the kidney often associated with kidney stones, may be a deferral for bone donation.
13	Did he/she have any history of high blood pressure (hypertension) or high cholesterol?	A long-standing history of poorly controlled hypertension increases risk of heart disease and may affect which organs/tissues can be donated. High cholesterol, or hyperlipidemia, is also identified as a cardiac risk factor.
14	Did he/she ever receive CPR, or have a history of any heart disease, condition, or injury such as: • rheumatic fever, • congenital heart disease, • coronary artery disease or previous coronary bypass surgery, • valvular disease, • bacterial or fungal endocarditis, • viral myocarditis, • Marfan's disease, • cardiomyopathy, • penetrating cardiac injury, or • chest pain?	Relates to suitability as a heart or heart valve donor. History of cardiac surgery and cardiac defibrillation will be evaluated on a case-by-case basis. CABG is an absolute exclusion for valve donation. History of bacterial endocarditis, rheumatic fever or semi-lunar valvular disease, cardiomyopathy of viral or idiopathic etiology, or Marfan's disease will help evaluate suitability of heart and/or heart valve for donation. Penetrating cardiac injuries and CPR will be evaluated on an individual case basis.
15	Did he/she have any family history of • diabetes, • hypertension, • coronary artery disease, or • stroke?	Screening for potential comorbidities with known or suspected genetic/hereditary links. Information is gathered and used for organ transplant teams and tissue banks to evaluate medical suitability.

16	Did he/she have any history of circulatory problems of the arms and legs, such as: • varicose veins, • phlebitis, • vasculitis, • venous insufficiency, or • deep vein thrombosis?	Evaluation of organ(s) and vasculature. Useful to determine quality of organ graft and assess potential need for additional vessels during organ transplant procedure.
17	Did he/she have any history of lung disease such as: • asthma, • emphysema, or • COPD ?	Evaluates medical suitability of lungs. Patient with COPD may be given steroids as part of long-term therapy. Length of steroid use is an important piece of information when evaluating suitability for donation.
18	Did he/she ever have any liver disease, including hepatitis, or jaundice?	Not all incidences of jaundice or liver diseases are cause for exclusion. Hepatitis A does not have a carrier state and is therefore less likely to be transmitted to recipients. Determining the type of hepatitis, when it occurred and treatments provided will aid programs in determining suitability.
19	Did he/she have a colonoscopy or any history of digestive or intestinal problems, such as: • ulcerative colitis, • bloody stools, or • Crohn's Disease?	Crohns' disease and Ulcerative colitis are thought to be autoimmune and may lead to deferral. Any suggestion of symptoms associated with cancer requires follow up.
20	Did he/she have any history of neurological or brain disease, such as: • epilepsy • Alzheimer's, • dementia, • stroke, • Parkinson's, • encephalitis, • meningitis, • any prion-related disease, such as Creutzfeldt-Jakob disease (CJD or any form of mad cow disease), or • any family history of CJD, Parkinson's, or dementia?	Donors with degenerative neurological diseases are excluded from tissue donation. The etiology of many neurological degenerative diseases is unknown or may be suspected to be of slow viral origin. Approximately 10% of reported CJD cases are due to an inherited susceptibility to the disease. Donors who are a blood relative (parent, child, sibling) of someone with familial-type CJD are considered at risk for transmission of CJD.
21	Did he/she recently experience any of the following symptoms: • memory loss, • seizures, • confusion, • spontaneous rippling or twitching of muscle • unsteady gait or • speech problems?	These symptoms may indicate CJD or other neurological disorders.

22	Did he/she recently experience symptoms such as: • headaches, • drowsiness, • neck stiffness, • loss of vision, • sensitivity to light, or • any unexplained neurological problems?	Some of the symptoms listed may indicate West Nile virus infection.
23	Was he/she ever diagnosed with or investigated for any autoimmune or chronic degenerative disorder, such as: • ALS (Lou Gehrig's disease), • Multiple Sclerosis (MS), • rheumatoid arthritis, • systemic lupus erythematosis (lupus), • polyarteritis nodosa, • thyroid disease, • sarcoidosis, or • myasthenia gravis?	If the donor has a history of autoimmune disease, the transplant physician(s) and/or tissue banks will evaluate the suitability for transplantation.
24	Did he/she have any bone or joint disease, such as: • osteoporosis, • arthritis, • osteomyelitis, or • metabolic bone disease, such as osteomalacia?	Cause of arthritis should be explored. Osteoarthritis, gout, osteoporosis or metabolic bone disease have a degenerative effect on bone. Further information regarding the diagnosis and treatment will aid in evaluating suitability to donate bones. Potential donors with stiff and sore joints caused by over-exercise may still be acceptable for organ and/or tissue donation.
25	Did he/she experience any periods of unexplained weight loss or have any blue or purple spots on the skin or mucous membrane?	These symptoms could indicate a serious active viral process, such as HIV, or cancer.
26	Did he/she have any history of skin conditions or disease, such as: • infection, • eczema, • dermatitis, • leprosy, • inflammatory skin diseases • abrasions, or • sores in the mouth or on the skin?	Important information when evaluating suitability of skin for donation. A systemic infection such as leprosy would require follow up. For organ donors, if psoriasis is identified, consider use of Tegison, a drug previously used to treat psoriasis that is potentially hazardous to recipients.

Blood / Blood Products / Tissues		
	Question	**Rationale**
27	Did he/she ever receive a transfusion of blood or blood products? In what countr(ies)?	Questioning whether the donor has received blood products will assist in identifying hemophilia. Potential donors who receive blood or blood products from screened blood donors are not excluded. When transfusion results in dilution of donor blood attempt to obtain a pre-transfusion specimen where possible. Many diseases can be transmitted via blood transfusion. Individuals who have received blood products in countries where certain diseases are endemic are at risk of transmitting these diseases to transplant recipients. Some high-risk countries include: Africa, Mexico, Central & South America and some parts of the United States. * Hemophiliacs (and their partners) are not eligible for donation if they have received human derived clotting factors, with the preceding 5 years. *** This requirement only applies to tissue donors, under the AATB/EBAA Standards.**
28	Did he/she ever use or take human-derived pituitary growth hormones? (In what country(s)?)	Human derived pituitary growth hormone has been associated with the transmission of Creutzfeldt-Jakob Disease (Genetically engineered growth hormone does not pose a risk). In North America and most other countries, it was no longer being distributed after 1985.
29	Was he/she ever refused as a blood donor or told not to donate blood?	Reason for refusal should be ascertained. A positive test for hepatitis B surface or core antigen; or noted antibody to hepatitis C, HIV, or HTLV-I or –II; is an automatic exclusion for tissue donation. Other conditions that preclude blood donation such as heart disease, low hemoglobin, low weight or abnormal blood chemistry may not necessarily be reason for exclusion.
30	Did he/she ever receive an organ or tissue transplant, such as a: • kidney, • dura mater, • cornea, • bone, • skin, or • heart valve?	Transmission of CJD has occurred with transplanted human cadaveric (allogeneic) dura mater. Post-transplant drug regime associated with organ transplant recipients precludes tissue donation because of the effects of drug therapy. There is always a risk of disease transmission when someone has received an organ or tissue transplant. Need for a transplant may indicate previous medical conditions such as viral hepatitis, which may preclude donation.

31	Did he/she ever have a transplant or medical procedure that involved live cells, tissues or organs from an animal?	Transplant of tissue from an animal origin (xenotransplant) may include tissue or products recovered from baboons, pigs, goats, sheep, cows, and mice. Xenotransplant **does not** include non-living cells, organs or tissues such as porcine insulin or porcine heart valves. Xenotransplantation poses a risk of cross-species transmission of undetected or unidentified infectious agents from animal origin, which may have significant outcomes for immune-suppressed recipients, and is also a risk of transmission to the general public. Although no clinical trials have been approved and not routine medical practice in Canada, procedures involving tissues of animal origin have been known to be used in the treatment of Parkinson's, Type I Diabetes, and burn survivors.
Infections / Infectious Diseases		
Question		**Rationale**
32	In the past 12 months, has he/she been investigated, diagnosed, or treated for any type of infection, such as: • Epstein Barr Virus (EBV), • Cytomegalovirus (CMV), or • Toxoplasmosis?	Certain types of viral or bacterial infection or infection of unknown etiology may pose a risk to immune-suppressed recipients. Determining the type of infection, treatment received and when the infection was resolved will aid in evaluation of organ and tissue donor suitability.
33	Has he/she ever been quarantined, investigated, diagnosed, or treated for an emerging infectious disease (e.g.Tuberculosis, Zika, MERS or Ebola)?	Evaluate the possibility of Tuberculosis, MERS, and/or Ebola, and/or Zika, and/or other transmissible infection. If symptoms exist, consider reviewing Health Canada's most recently issued Travel Health Advisory at http://www.phac-aspc.gc.ca/tmp-pmv/pub-eng.php to identify whether potential donor was exposed to areas viewed as conferring increased risk of transmissible disease. Most people infected with Zika virus won't even know they have the disease because they won't have symptoms. The most common symptoms of Zika are fever, rash, joint pain, or conjunctivitis (red eyes). Other common symptoms include muscle pain and headache. The incubation period (the time from exposure to symptoms) for Zika virus disease is not known, but is likely to be a few days to a week.
34	Has he/she ever had direct contact with or exposure to a place or person who is known or suspected to have an emerging infectious disease (e.g. Tuberculosis, Zika, MERS, Ebola)?	
35	In the last 3 weeks, has he/she or any family member living in the immediate household had any symptoms, such as: • unexplained weakness or fatigue, • persistent or frequent cough, • swollen lymph nodes, • nausea or vomiting, • persistent diarrhea,	

	• fever over 38°C with headache, • any fever, • any headache, • rash, • joint pain, • conjunctivitis (red/pink eye), • night sweats, • muscle aches, or • shortness of breath?	
36	Has he/she ever been told by a health professional that they were suspected or known to have West Nile Virus, based on symptoms, exposure to, or a positive test for West Nile Virus within the last 120 days?	West Nile Virus is transmitted from mosquitoes to humans, and occurs in North America. There have been reported cases of WNV transmission through blood transfusions and organ transplants. While there have not been any reports of tissue transplant transmission, WNV screening helps assess risk factors. Persons who have had a medical diagnosis or suspicion of West Nile virus (WNV) infection (based on symptoms and/or laboratory results, or confirmed WNV viremia) should not be considered for tissue donation for up to and including 120 days following diagnosis, or onset of illness, whichever is longer, unless a Medical Director has been advised of this finding and has approved the use of the tissue.
37	Has he/she been bitten by an animal in the past year?	Gathering information regarding specifics about the animal bite will help evaluate risk. Non-bite exposures to rabies are very rare. Scratches, abrasions, open wounds, or mucous membranes contaminated with saliva or other potentially infectious material (such as brain tissue) from a rabid animal constitute non-bite exposures. There has also been documented non-bite transmission of rabies (aerosol transmission) in laboratory workers exposed to concentrated aerosols of rabies virus. Purported aerosol transmission to humans has been associated with working in caves inhabited by millions of bats, however, aerosol transmission is exceedingly rare and conditions under which it may occur are unique. Human cases of rabies in North America have largely been associated with bat rabies virus variants. * Contact with bats, including a history of bats inside the living area or being bitten or scratched by a bat may pose a rabies risk. There have been cases of rabies transmission where contact with a bat must have occurred while the affected individuals where sleeping. The incubation period for rabies can be longer than a year. Recent cases of rabies transmission to transplant recipients from an infected organ donor have occurred.
38	Did he/she ever have contact* with a bat or bats? *contact defined as history of a bat inside the living area or been bitten or scratched by a bat.	

39	Has he/she ever had a positive skin test for, been diagnosed with, or ever been treated for tuberculosis?	Tuberculosis is a disease caused by *Mycobacterium Tuberculosis.* It may affect the lungs or other organs such as kidneys, brain or spine. There are approximately 1600 new cases of TB reported in Canada every year. High risk groups in Canada include: urban homeless, individuals in long term care facilities and correctional institutions, immigrants and people who work with these groups. TB can occur as an active infection or a latent (asymptomatic) infection. Evaluation of potential donors relies on medical history, physical exam and chest radiographic examination. A reported history of flu-like symptoms, persistent cough, positive Mantoux skin test, history of an interferon gamma release assay for latent TB (test used as an adjunct to the Mantoux test on individuals who have received BCG vaccine) and/or suspicious chest x-ray requires further investigation and CMO discussion. Individuals from European countries where TB is prevalent may have received a preventive vaccine called BCG. A history of this may result in a positive skin test and is not necessarily indicative of active infection. Risk of developing TB is high in immune-suppressed recipients.
40	In the past 12 month, did he/she have any vaccinations or immunizations? (e.g., Shingles, Chickenpox, MMR, Yellow fever, BCG, Oral typhoid, Smallpox)	Date of vaccination is important in evaluating medical suitability. *Live vaccine* within 4 weeks may be a reason for deferral. - 2 weeks for rubella, yellow fever, and oral polio (Sabin) - 4 weeks for German Measles, MMR & Varicella Zoster - The following do not need to be deferred: *Toxoid or killed virus vaccinations* including anthrax, paratyphoid, pertussis, plague, polio (Salk), Rocky mountain spotted fever, tetanus, typhoid, and typhus. In smallpox vaccination, the post-vaccination scab may contain the vaccinia virus so it is helpful to know when the scab fell off. If there were complications from the smallpox vaccine, a greater risk of viral infection in the blood exists, and is therefore a greater risk of transmission to the recipient. Increased risk of transmission is identified if complications from the vaccine existed within 14 days of donor evaluation.
41	Did he/she know anyone who had a smallpox vaccination?	Individuals who come in close contact with the vaccination site (i.e., during bandage changes) while it is healing may develop vaccinia virus. Vaccinia virus is a “pox” type virus that may cause a rash, fever, head and body aches. It is Important to know the type of contact and when it occurred to evaluate suitability. **This question only applies to tissue donors, under the AATB/EBAA Standards.**

42	In the past 12 months, has he/she been exposed to any blood or body fluids known or suspected to be contaminated by HIV, HTLV, or Hepatitis B or C? (Possible routes of transmission may include accidental needle stick, contact with open wounds or non-intact skin, and mucous membranes.)	Direct exposure to potentially contaminated blood poses an increased risk of bloodborne infectious diseases transmission either through percutaneous entry or through carriage via bodily fluid contact.
43	Did he/she ever have a positive test for Hepatitis B or C? Did he/she ever receive treatment for Hepatitis C?	Exposure, close contact (living in the same household) or sexual relations with another individual with clinical hepatitis caused by A, B, C or non-A, non-B may lead to exclusion for tissue donation. Organ donation is not definitely excluded but evaluated according to risk - benefit to recipient. Donors that have received treatment for Hepatitis C in the last 12 weeks, donors that are currently receiving treatment for Hepatitis C, and donors with a past diagnosis of Hepatitis C for which the treatment details are unknown may not have accurate Hepatitis C serology and/or Hepatitis C NAT testing results. These donors should be allocated as if they were Hepatitis C NAT positive as a risk for transmission of the Hepatitis C virus may still be present.
44	In the past 12 months, did he/she have close contact with anyone having clinically active HBV or clinically active HCV infection? Close contact is defined as repeatedly and regularly sharing the same living space with someone.	Exposure, close contact (living in the same household) or sexual relations with another individual with clinical hepatitis caused by B, C or, non-B may lead to exclusion for tissue donation. Organ donation is not definitely excluded but evaluated according to risk - benefit to recipient. Clinically active HBV is defined as positive viral DNA present in blood with new immunity and positive Hepatitis B Surface Antigen. Clinically active HCV is defined as positive viral RNA in blood. **If answered yes or unknown, the organ donor must be exceptionally distributed.**
45	Was he/she ever tested for or diagnosed with HIV or HTLV?	If the donor was tested for HIV, it is important to determine why the testing was done to assess for risk factors.
46	Has he/she ever had a travel-related disease such as: • Malaria, • Chagas Disease, • Babesiosis, • Leishmaniasis, or • Zika?	All of the above listed conditions may be transmitted via organ or tissue transplant. Malaria is transmitted by mosquitoes in endemic regions such as Africa and causes flu-like symptoms.

47	Did he/she ever receive immunization or treatment, including preventative, for a travel-related disease?	Chagas is transmitted by blood-sucking insects called triotomine bugs (also called the kissing bug), which dwell in poorly constructed houses in Mexico, Central and South America. This disease causes enlarged lymph nodes and can impact heart and liver function. Babesiosis is transmitted by a tick bite and is endemic in parts of the USA and Europe. The disease can cause flu-like symptoms and may impact heart, liver and kidney function. Leishmaniasis is transmitted by the sand fly in endemic regions <88 countries worldwide> including Central and South America, Mexico, Southern Europe, Asia, the Middle East and Africa. It can affect organs such as spleen and liver or it may only affect skin. Suitability for transplant will be evaluated on a case-by-case basis. Zika virus is a flavivirus transmitted by Aedes mosquitoes, predominantly, the *Aedes acgypti* species. The mosquito primarily bites during the day and is the same type of mosquito that transmits Dengue and Chikungunya. On Monday February 1, 2016, the World Health Organization (WHO) declared the spread of Zika Virus an international public health emergency due to the temporal and geographic association with the cluster of cases of congenital anomalies, mainly microcephaly in the Western hemisphere. ODOs must obtain the travel history of organ/tissue donors. If this information indicates that the donor has returned from a Zika affected area in the past 21 days, then this information should be communicated to transplant teams so they can weigh the risks of potential Zika Virus transmission against the benefits of organ/tissue transplantation on a case by case basis. It is recommended that tissue banks not undertake donation from individuals with a medical diagnosis of Zika Virus infection in the past 6 months.
Eye Donors: If donating eyes, complete the following questions. If no, skip to Question 50.		
	Question	**Rationale**
48	Did he/she ever have any of the following: • eye disorder, • eye infection, • previous eye surgery (including laser surgery), • glaucoma, • cataracts, • corneal disease, • eye tumors such as retinoblastoma or pterygium, or • any other eye disorders including infection or inflammation?	Provides history of eye health and information about suitability for eye donation. Active infection, previous corneal surgery, eye tumours, or opacities of the cornea *may* result in deferral for eye donation.

49	Was he/she ever treated for congenital Rubella or Reyes Syndrome?	Persons born with Rubella infection frequently have eye defects. Reyes syndrome may affect quality of corneas.
Lifestyle		
	Question	**Rationale**
50	Did he/she ever smoke tobacco products, marijuana or vape (inhale vapors produced by an electronic device)?	May relate to suitability as a heart and/or lung donor. The inhalation of tobacco products, marijuana and/or vapors produced by electronic devices may increase the incidence of cancer, cardiac and pulmonary diseases. Type of products used, amount used daily and length of use in number of years is important.
51	Did he/she drink alcohol?	May relate to suitability as a liver or pancreas donor. The nutritional effects of alcoholism have an impact on the quality of tissue. It is important to obtain information regarding the amount of alcohol used.
52	Did he/she ever use or take drugs, such as: • marijuana, • steroids, • cocaine, • amphetamines, • anything not prescribed by his/her doctor, or • overuse of medication prescribed by his/her doctor?	Provides information about behaviours considered high risk. Gathering specific information about drug use in terms of timing, how used, frequency of use and which drugs, is necessary to evaluate the risk. Intravenous drug use is an exclusion for tissue donation. Intranasal cocaine use within 12 months may exclude tissue donation due to the high risk of Hepatitis C transmission. Cocaine use may preclude heart donation for transplant [related to effects of cocaine use on the heart (cardiomyopathy)]. Certain drugs may have pulmonary effects and result in preclusion lung donation. Donor suitability is evaluated on a case-by-case basis.
53	In the past 12 months, did he/she have tattooing, ear/body piercing, electrolysis, acupuncture, or permanent make-up?	Percutaneous contact of blood and body fluids during the preceding 12 months may lead to exclusion due to the high risk of infectious disease transmission (in cases where activities performed under non-sterile conditions). Detailed information about the event is helpful in evaluating the risk.
54	Was he/she ever in a youth correctional facility, jail, lockup, or prison?	Tissue donation is excluded if the donor has been incarcerated for more than 72 hours in the past 12 months due to the increased prevalence of HIV in this population. Tuberculosis is a disease caused by *Mycobacterium Tuberculosis.* It may affect the lungs or other organs such as kidneys, brain or spine. There are approximately 1600 new cases of TB reported in Canada every year. High risk groups in Canada include: urban homeless, individuals in long term care facilities and correctional institutions, immigrants and people who work with these groups. TB can occur as an active infection or a latent (asymptomatic) infection. Evaluation of potential donors relies on medical history, physical exam and chest radiographic examination. A reported history of flu-like symptoms, persistent cough, positive Mantoux skin test, history of an interferon gamma release assay for latent TB (test used as an adjunct to the Mantoux test on individuals who have received BCG vaccine) and/or suspicious chest x-ray requires further investigation and CMO discussion. Individuals from European countries where TB is prevalent may have received a

		preventive vaccine called BCG. A history of this may result in a positive skin test and is not necessarily indicative of active infection. Risk of developing TB is high in immune-suppressed recipients.
55	Did he/she ever experience homelessness or live in a homeless shelter?	Tuberculosis is a disease caused by *Mycobacterium Tuberculosis.* It may affect the lungs or other organs such as kidneys, brain or spine. There are approximately 1600 new cases of TB reported in Canada every year. High risk groups in Canada include: urban homeless, individuals in long term care facilities and correctional institutions, immigrants and people who work with these groups. See rationale for question 54.
Sexual History		
As a reminder, the following questions are of a sensitive and personal nature. These questions are required to be asked of all potential donors. The following questions pertain to his/her sexual history. Sexual activity and sex refer to any method of sexual contact including vaginal, anal, and oral.		
	Question	**Rationale**
56	In the past 12 months, did he/she have any sexually transmitted diseases, such as: • syphilis, • gonorrhea, • genital herpes, • genital warts, or • HPV?	Recent positive diagnosis or treatment for certain sexually transmitted diseases may be indicative of a history of unprotected or high-risk sexual behaviour. Organ suitability is assessed on a case-by-case basis when a sexually transmitted disease is identified. A positive response to this question may be identified as a contraindication to tissue donation.
57	Did he/she ever live with or have sex with anyone who received an organ or tissue transplant from an animal?	(see question 32) – close contact with a recipient of tissue or organ from an animal origin increases risk of transmission of undetected, unidentified, or known infectious agents of animal origin, such as CJD.
58	Did he/she ever live with or have sex with anyone who was born in or who lived in Africa after 1977?	HIV and malaria are endemic in many areas of Africa. **This question only applies to tissue donors, under the AATB/EBAA Standards.**
59	In the past 5 years, has he/she been a victim of sexual assault or rape?	A person who has been a victim of sexual assault or rape may be susceptible to transmissible diseases.
60	In the past 5 years, has he/she been sexually active even once?	A person sexually active in the past 5 years may be susceptible to high-risk behavior and transmissible diseases associated with current or previous sexual partner(s). If sexually inactive within past 5 years, check off the 'N/A' box for the additional questions (#61 - 70) regarding sexual partners and sexual history.
61	In the past 5 years, did he/she have sex in exchange for money or drugs?	Individuals who engage in indiscriminate sex cannot account for their partner's sexual history and therefore cannot be properly screened. This population also has an increased prevalence of HIV as well as other communicable diseases.

62	**Male Donors Only:** In the past 5 years, did he have sex with another male?	There is an increased prevalence of HIV in this population. • **The 5-year period only applies to tissue donors, under the AATB/EBAA Standards.** • **A 12-month period applies for Organ donors.**
63	In the past 12 months, did he/she have sex with a person who has (a) had male to male sexual relations in the past 5 years or (b) whose sexual partner has had male to male sexual relations in the past 5 years?	Individuals answering yes to the prior 4 questions have increased risk of exposure to HIV as well as other communicable diseases. Despite serological testing, a period of undetectable viremia may occur. **63.) The 5-year period only applies to tissue donors, under the AATB/EBAA Standards.** • **A 12-month period applies for Organ donors.**
64	In the past 12 months, did he/she have sex with a person who has had sex in exchange for money or drugs in the past 5 years?	
65	In the past 12 months, did he/she ever have sex with a person who used a needle to inject drugs that were not prescribed by their own doctor in the past 5 years?	
66	In the past 12 months, did he/she have sex with any person known or suspected to have HIV, HTLV, or Hepatitis B or C?	Human T-Lymphotrophic Virus type l and ll are sexually transmitted diseases that are often asymptomatic. HTLV l is common in Japan and Caribbean countries. Type ll is prevalent in certain groups, such as North American aboriginals and IV drug users. Type l is associated with adult T-Cell leukemia (ALT), lymphoma and/or HTLV associated myelophathy (HAM). Type ll disease process is less certain. Immune-suppressed recipients are at increased risk of developing any of the above-mentioned conditions in the presence of HTLV. HBV and HBC may be transmitted through sexual contact and shared needles. HBV/HBC may not be detected during the early stages of the virus. They are both transmitted via organ and tissue transplant
67	In the past 12 months, did he/she have sex with a person who has been exposed to any blood or body fluids known or suspected to be contaminated by HIV, HTLV, or Hepatitis B or C? (Possible routes of transmission may include accidental needle stick, contact with open wounds or non-intact skin, and mucous membranes.)	Individuals answering yes to the prior 4 questions have increased risk of exposure to HIV as well as other communicable diseases. Despite serological testing, a period of undetectable viremia may occur.
68	In the past 12 months, did he/she have sex with any person known to have hemophilia or other clotting disorders that required transfusion of blood or blood products such as human derived clotting factor concentrates?	See prior question regarding hemophilia and blood transfusions. Many diseases are transmitted through both blood transfusions and sexual contact. **This question only applies to tissue donors, under the AATB/EBAA Standards.**

69	In the past 12 months, did he/she have a sexual partner whose sexual background was unknown?	Where a potential donor's sexual partner(s) history is unknown, HIV exposure, as well as other communicable diseases cannot be fully assessed.
70	In the last 21 days, has he/she had sexual contact with a man who is known to have either: A) A known, or suspected medical diagnosis of Zika Virus infection within six months prior to the sexual contact, **OR** B) Resided in, or travelled to an area with active Zika Virus transmission within the past 6 months	See rationale document for question 47. As well, it is also recommended that this approach be adopted when the donor has had sexual contact in the past 21 days with a man who is known to have had a medical diagnosis of Zika Virus infection within six months prior to the sexual contact or who resided in, or travelled to, an area with active Zika Virus transmission within the past six months.
Travel		
	Question	**Rationale**
71	a. Travel History:Did he/she travel/live outside of Ontario and/or outside of Canada in the past six months? b. Did he/she spend a COMBINED TOTAL of more than one month outside of Canada? • Rural Mexico, and/or Central America, and/or South America (for a combined duration up to 3 months or more) • United Kingdom (England, Northern Ireland, Scotland, Wales, Isle of Man or Channel Islands) and/or France (for a combined duration of 3 months or more between January 1, 1980 to December 31, 1996) • Europe includingthe United Kingdom or France (for a total of 5 years or more since January 1, 1980) • Travelled in the preceding 56 days to areas where WNV is endemic c. Did he/she ever live on a military base outside Canada?	Travel history must include travel both within Canada as well as anywhere outside of Canada. One of the reasons behind this requirement is that certain geographic regions are considered by Health Canada and the US Centers for Disease Control and Prevention to be endemic for certain transmissible diseases. For this reason, a donor's history with respect to travel and residency could place them at higher risk for certain transmissible diseases, such as West Nile virus, SARS, malaria, yellow fever and other infections. The following links contain information with respect to malaria endemic regions: Public Health Agency of Canada: https://travel.gc.ca/travelling/health-safety/travel-health-notices US Centers for Disease Control (CDC): http://www.cdc.gov/malaria/travelers/country_table/a.html World Health Organization (WHO): http://www.who.int/malaria/travellers/en/ Chagas disease is endemic in some regions of Mexico, Central and South America, and is more likely to be acquired by visiting these regions for an extended period of time. Determining the amount of time spent in either the UK and/or France and between January 1, 1980 to December 31, 1996 provides some estimation of risk for CJD. **The Europe (including the United Kingdom or France) travel exclusion only applies to tissue donors, under the AATB/EBAA Standards.** Determine the amount of time spent in Europe (excluding the UK or France) for a total of five years or more since January 1, 1980. European countries that have increased risk include: Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Czech-Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Macedonia, Netherlands, Norway, Poland, Portugal, Romania, Slovak republic, Slovenia, Spain, Sweden, Switzerland, and Yugoslavia. Additionally there is increased risk for any tissue donors who resided at US military bases in Northern Europe (Germany, Belgium

		and the Netherlands) for 6 months or more from 1980 to 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more from 1980 to 1996. Donors who have travelled to an area where WNV is endemic in the preceding 56 days should be tested for WNV and results may be provided to the transplant programs following organ distribution. Details must be provided for any of the above or other locations, specifying where, date(s) and durations(s).
72	In the last year, has he/she travelled to an area or been in contact with someone who has travelled to a location listed on a travel advisory for communicable disease?	Contact with someone who has travelled to a location listed in a travel advisory for a communicable disease was added as it was a gap in screening. The travel time or contact period may exceed 21 days for some diseases. The types of diseases and advisories change from time to time. This question needs to address a wide range of diseases, advisories, and all stakeholder requirements. Increasing the time period and adding specifications for both the time period of travel and the reason for the advisory if a positive answer is given allows all stakeholders to implement specific stakeholder criteria and appropriate level of risk. Evaluate the possibility of contact or infection with MERS , Ebola, or other transmissible diseases. Travel advisories are issued by Health Canada and all current advisories in effect are available at the Public Health Agency of Canada website. https://travel.gc.ca/travelling/health-safety/travel-health-notices Travel in the last 30 days to an area listed in the Travel advisory for Ebola would rule out a patient from organ donation.
Paediatric Donors: If the donor is 18 years old or greater, select N/A for Questions 73 to 77		
Question		**Rationale**

73	Was the child born to a mother who had or was at risk for HIV or hepatitis infection?	**See rationale for # 74 - 75**
If the child is less than 11 years old, complete Questions **74** to **77** below If no applicable, select N/A for Questions **74** to **77**		
74	In the past 12 months, was the child breast-fed or did they receive breast milk?	HIV can be transmitted through breast milk from HIV infected women to their children. Until a child is 18 months old, an HIV antibody test indicates maternal infection but does not definitively diagnose infection in the infant. A separate questionnaire completed by the mother is required if 'yes' is the answer to any of the paediatric questions (maternal serology is also required). If the mother meets the behavioural or laboratory exclusion criteria for adult donors (regardless of HIV status), the child should not become a donor unless HIV infection can be definitely excluded as follows: • Children greater than 18 months of age, who are born to mothers with, or at risk for HIV infection, who have not been breast fed within the past 12 months, and whose HIV antibody test, physical examination and review of medical records do not indicate evidence of HIV infection can be donors. • Children less than or equal to 18 months of age who are born to mothers with or at risk for HIV infection and/or who have been breast fed within the past 12 months should not be accepted as tissue donors regardless of their HIV test results. Suitability for organ donation is evaluated on a case-by-case basis. •
75	Was the child less than or equal to 18 months of age?	
76	Did the mother receive any type of pre-natal care?	General health information for medical evaluation. Describe in terms of excellent, good, poor. This may be significant if the baby was born in another country.
77	How would you describe the mother's health during the pregnancy?	
All Donors		
Question		**Rationale**
78	Are you aware of any other medical conditions that we have not discussed?	Provides historian the ability to raise any medical or social issues that may potentially affect medical suitability that have not been addressed by the identified questions in the questionnaire.
79	After completing this questionnaire, is there any reason to believe that the donated organs and/or tissues may not be suitable or safe for transplantation?	The intent of this question is to allow the interviewees the opportunity to stop the donation process instead of outwardly disclosing sensitive information regarding the donor. If the answer is "yes" and the interviewee does not wish to reveal further details, the donor will be deferred for tissue donation. Organs may be used according to the risk/benefit as determined by the medical director and the transplant physician(s).

80	Are there any other individuals that may provide more personal or additional information regarding any of these questions?	From time to time, the historian answering the questionnaire may know either the medical history or social history, but not both. For example, a sexual partner or roommate may have more pertinent sexual or social history details than the legal next of kin, who may have more information on medical details, or vice versa. If there may be someone who knows the donor better than the historian who is providing the information, reasonable effort is made to contact this person to review a new questionnaire so as to obtain as complete a history as possible.
81	Have funeral arrangements been made or do you know which funeral home you will be using?	Useful information to determine timelines and contacts for follow-up/communication with funeral homes, if necessary. Often, funeral homes may have additional contact information for next of kin or alternative historians.

Additional Comments

If there are any discrepancies in the answers given (e.g., contradicting or inconsistently answered questions, etc), please provide the number of the question(s) involved and further details as to why the interviewee may have answered in this manner (e.g., Infidelity may result in inconsistent answers being given in in the Sexual History Questions, #'s 55 to 69). Please provide as much details as possible in the Additional Comments section.

References & Resources

Note: References listed are current as accessed at time of initial publication of this document. While TGLN will periodically update document to ensure content presents the most current clinical information, TGLN cannot be held accountable to the viability of links and resources after time of publication.

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