#### Introduction

The purpose of donor characterisation is to determine whether a potential donor is suitable to donate **any** organ or tissue, and then to determine **which** organs and tissue can be donated. Whilst following assessment of an individual's medical and social history, organ and tissue donation may be possible, it may be that not all organs or tissues are suitable due to specific organ/tissue requirements.

This document aims to provide a rationale for specific information that is required to assess a potential donor's suitability for organ/tissue donation and should be used in conjunction with the NHS Blood and Transplant **FRM4211** Medical and Social History Questionnaire (MaSH).

The purpose of the MaSH questionnaire is to collate relevant information for donor characterisation; this can help determine risk factors for the transmission of disease from donor to recipient. It is the responsibility of the Specialist Requestor/Specialist Nurse Organ Donation/Specialist Nurse Tissue Donation/Tissue Donor Co-ordinator to collect comprehensive information on medical, behavioural and travel history and relay all the information obtained to the organ recipient and tissue procurement centres. In addition, for organs it is the responsibility of the implanting surgeon to assess the risk-benefit of transplant for their individual patients. For tissue, the final decision on donor acceptance is often made after reviewing additional information available post donation and it is the responsibility of the tissue establishment to make the final decision on donor suitability.

All specialist nursing staff trained to use this document must recognise when to expand questions in order to obtain more details, what additional information might be required and recognise when to seek advice. It is expected that the donors referred for tissue donation meet donor selection guidelines (see link below) or have had an individual risk assessment on donor suitability.

The conditions which will cause the deferral of a potential donation vary significantly between organs and tissue, including ocular tissue. For many of the questions asked, the principle will be to gain as much relevant information as possible, clearly document the information and inform recipient centres. For tissue donation this is also relevant, however suitability can also be confirmed by reference to the current version of the UKBTS Tissue Donor Selection Guidelines for Deceased Donors (TDSG-DD) (<u>http://www.transfusionguidelines.org.uk/dsg/ctd/guidelines</u>).

This rationale is a guide and should not replace discussions with transplant centres, tissue establishments, microbiologist, and other experts where necessary. SaBTO guidance on the microbiological safety of human organs, tissue and cells used in transplantation will also provide more information on many of the questions below. <u>https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/680745/sabto-microbiological-safety-guidelines.pdf</u>

### PATIENT ASSESSMENT SECTION

Whilst the MaSH document does give 'unknown' as an option to minimise organ/tissue deferrals, it is preferred wherever possible this option is not used. As such when opening the conversation with the family, we request they answer with 'yes or no.'

In terms of the country of residence question, you are classed as a resident if you have lived somewhere for 6 months and over.

Question	Reason for asking the Question	Additional Action to take re Organ Donation	Additional Action to take re Tissue Donation
FOR PAEDIATRIC DONATION: has your child been breast-fed in the past 12 months?	There is a risk of vertical transmission of some blood borne viral infections from the mother to her child via breast milk. Although testing of the milk donor would be desirable, it is acknowledged that this may not be possible, and this should not be a contraindication for donation; discuss accordingly. Transplant centres should be informed. Prior to donating breast milk, microbiological screening will have been carried out in the maternity unit.	The mother's medical, social, and behavioural history should be assessed and both a maternal and infant blood sample must be taken for full microbiological screening.	As organ donation.
NOTE: for all patients under the age of 18 months and any child who has been breast-fed in the last 12 months, a blood sample for microbiological testing is required from the mother, as well as from the patient.	Some infections can be transmitted from the mother in utero, at birth, perinatally and through breast feeding. Examples of some of those blood borne viruses, which are also transmissible by transplantation, are CMV, HIV, HBV, HTLV and HCV. Testing the mother identifies potential infectious risk for the baby and if positive, will inform need for further testing in the case of organ donation; for tissue donation, positive maternal results is a contra-indication for infant donation. (see additional action on the right). Donor characterisation testing portfolio has expanded over time; to avoid difficulties in obtaining sufficient blood sample from small babies, there are instances when a maternal sample can be used as a surrogate.	<ul> <li>In the case of deceased neonatal or infant donors the following blood samples are required:</li> <li>A maternal sample is required when an infant is less than 18 months of age or when an older child has been breast fed within the 12-month period prior to donation.</li> <li>For still births and neonates less than 48 hours after birth, no sample is required.</li> <li>For neonates between 48 hours and 28 days after birth, a sample riss of possible viral transmission, e.g. receiving blood components/products or undergoing a surgical procedure.</li> <li>For infants more than 28 days after birth, a sample is always required.</li> </ul>	As organ donation. In line with JPAC guidance, an additional maternal blood sample for microbiology testing will be required when facilitating tissue donation. Under EU Tissues & Cell Directive, <u>if</u> the mother is infected with <u>HIV/HBV/HCV/HTLV or is at risk of</u> <u>these infections</u> , an infant under the age of 18 months or who has been breastfed in the past 12 months <u>cannot</u> <u>be accepted as a tissue donor</u> regardless of the results of the tests; maternal sample is required to establish mother's status and assess donor suitability.
For ALL female patients aged between 12 and 55 years of age* Is there a possibility that your relative could be pregnant?	There is a requirement to establish pregnancy status in female organ donors, this is standard best practice for females of childbearing age undergoing surgery. *DonorPath currently displays age range 13-53 years. This does not reflect current clinical guidance of 12-55 years documented in <b>MPD891</b>	If pregnancy is confirmed or suspected, the donation process should be paused, and expert advice should be sought to enable individual case assessment.	No action required.



GENERAL HEALTH INFORMATION Was/did your relative or you (if completing as mother of paediatric donor):				
Question	Reason for asking the Question	Additional Action to take re Organ Donation	Additional Action to take re Tissue Donation	
<ol> <li>Did your relative visit a general practitioner in the last two years?</li> <li>Was your relative currently seeing or waiting to see a general practitioner or any other healthcare professional?</li> </ol>	These are broad questions to ascertain if there are any long term/current health problems. If the answer to either is yes, it is important to obtain as much information as possible including symptoms, diagnosis, investigations, and medications prescribed include names of hospitals if relevant to allow further clarification as required. <b>Note:</b> It is important to obtain accurate information on past/current medical history. Therefore, it is a requirement that the GP is contacted to complete the NHSBT GP questionnaire ( <b>FRM1602</b> ).	Attempts should always be made to contact the GP prior to the retrieval of organs. If following these attempts, the GP cannot be contacted, the NHSBT GP assessment <b>MUST</b> be sent by the next working day. Any new relevant information must be shared appropriately. If the patient has no GP, then ensure this is information is documented for recipient centres to be aware.	As organ donation.	
3. Did your relative ever take regular medication?	This is a broad question to ascertain if there are any long term/current health problems. Include type of medication, length of therapy and reason for treatment. Rationale for acne, prostate and psoriasis medication: Finasteride (prostate), Dutasteride (Avodart) or one of the following acne treatments: Roaccutane, etretinate, acitretin, isotretinoin, alitretinoin, tamoxifen and dutasteride - All these medications are teratogenic and are excreted from the body at different rates at different times and can therefore be transmitted through tissue.	Document information clearly to alert accepting surgeons.	Refer to TDSG-DD guidelines re deferral period required for each of the named drugs – if donation will take place beyond the deferral period accept donation; if donation takes place within the deferral period for the medication defer donor unless the tissue bank can perform individual risk assessment based on risk benefit analysis.	
4a.Did your relative have a history of allergies to medication, food, or other substances?	Aiming to establish all substances what the donor was allergic to; if the donor does have a history of allergy it is important to get information as to the type of allergy i.e. mild rash or severe anaphylactic type reaction. There is the potential that the organ recipient would develop the same type of allergy as the donor.	Document information clearly to alert accepting surgeons.	No action required.	
4b. Did your relative have any health problems due to exposure to toxic substances such as pesticides, lead, mercury, gold, asbestos, cyanide, agent orange etc?	Some toxic substances may linger in the body for several years and could potentially be transmitted through transplanted tissue/organs.	Document information clearly to alert accepting surgeons.	It is HTA requirement based on EU commission Directive 2006/17/EC that tissue donation from donors with the history of "ingestion of or exposure to a substance (such as cyanide, mercury, lead, gold) that may be transmitted to recipients in a dose that could endanger their life" must be excluded. Expert advice must be sought for individual risk assessment.	
5a. Was your relative a diabetic? If yes, were they on insulin?		If yes, absolute contraindication for pancreas and islet donation. Refer to <b>POL188</b> (Contraindications to Organ Donation).	If yes, absolute contraindication for pancreas and islet donation No action required for other tissues.	



Question	Reason for asking the Question	Additional Action to take re Organ Donation	Additional Action to take re Tissue Donation
5b. Is there a family history of diabetes? If yes, is it insulin- dependent diabetes?	Because diabetes can have an effect on a number of organs particularly development of diabetic nephropathy in the kidneys, this information helps inform transplant centres when considering organs for transplantation. Increased risk of kidney disease runs in families.		
6. Did your relative suffer from any chronic or autoimmune illness or disease of unknown cause?	Some diseases of unknown aetiology, such as multiple sclerosis, inflammatory bowel, and Crohn's disease, may have an as yet unrecognised infectious cause. More importantly, if there is a current condition that is suspected to be of infectious origin, but a cause has not been identified, there is a risk of transmission. Some chronic neurological or cardiac conditions for instance, may have an infectious aetiology which is unsuspected at time of death such as Chagas disease, a condition that is not commonly considered in the UK as it is not endemic.	Clinical assessment as appropriate. In light of other relevant information, including epidemiology, e.g. family or own history of gastrointestinal dysmotility, cardiac arrhythmia and residency in Chagas endemic area.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated.
7. Did your relative ever suffer from any bone, joint, skin or heart disease?	Responses will inform transplant centres and tissue establishments when assessing the patient's suitability to donate.	Document information clearly to alert accepting surgeons.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated.
8. Did your relative ever have hepatitis, jaundice, or liver disease?	Jaundice can have infectious causes, such as viral hepatitis, and non-infectious causes, such as gallstones. Enquire regarding dates, causes, diagnosis, investigations.	Document information clearly to alert accepting surgeons.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated.
9. Did your relative recently suffer from significant unplanned weight loss?	Recent unplanned weight loss may be an indication of illness, including malignancy. It is important therefore to obtain the reason for the weight loss, the estimated amount of weight loss, if it was investigated or accompanied by other problems.	Document weight loss information clearly to alert accepting surgeons.	As organ donation.
10. Did your relative ever undergo any investigations for cancer or were they ever diagnosed with cancer?	The presence, or previous history, of malignancy poses a risk of transmission of malignant cells to a recipient. If yes, obtain further information regarding dates, diagnosis, and treatments. If investigations such as mammograms, smear tests, PSA testing for prostate cancer and so on have been completed, ensure it is clearly stated whether these were part of routine national screening or due to any concerns or symptoms to allow a risk/benefit assessment of the likely implications.	It is important to assess the type, grade and time scales of any malignancy, as certain types are contraindicated in organ donation. Refer to <b>POL188</b> (Contraindications to Organ Donation).	If organ and tissue donation is contraindicated, corneal donation may be possible. Refer to current version of TDSG-DD.
11. Did your relative have a history of eye disease, receive any medications for eye problems (e.g. eye drops), or undergo eye surgery or laser treatment?	This question is specifically designed to assess the suitability of ocular tissue; of note, glaucoma surgery might involve the use of allogeneic scleral tissue and it is therefore important to elicit whether a patient with glaucoma has undergone surgery and where even if further surgical details are not known to the family at the time of the family interview	Not applicable to organ donation.	If answer yes to this question refer to current TDSG-DD as donation may be contraindicated.

Question	Reason for asking the Question	Additional Action to take re Organ	Additional Action to take re
		Donation	Tissue Donation
12. Did your relative ever have any operations?	If the answer is yes, it is important to obtain as much information as possible, such as reasons for surgery, as this may provide important past medical history. In particular, any operations for malignancy, neurosurgery, or operations where organs/tissue were transplanted.	Document information clearly to alert accepting surgeons.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated.
13. Did your relative ever have any surgery on the brain or spine?	Before 1993 dura mater from deceased donors, has been documented to transmit CJD, may have been used in brain and spinal surgery. Therefore, where this answer is yes, the patient is at increased risk of CJD. Clarity should be sought on type of procedure, dates, and location/hospital where procedure occurred.	Document information clearly to alert accepting surgeons.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated.
14. Did your relative ever have an organ or tissue transplant?	This will provide information regarding any previous requirement of immunosuppression, risk of CJD transmission if within specific time frames, and inform decision making. Include any family history of organ and/or tissue transplants and the reason for	Document information clearly to alert accepting surgeons.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated.
	transplant and record this information in the "Add Detail" box where all transplant centres can review this information.		
	passed from the donor to the recipient.		
	updated in future versions to add family history as above.		
15. Was your relative ever told not to donate blood?	If answered yes, reason for this must be clarified. Some deferrals are due to reasons such as a patient's age or weight, however there may be other reasons such as infection risk including being at CJD risk for public health purposes.	Document information clearly to alert accepting surgeons.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated.
16. Did your relative receive a transfusion of blood or blood product(s) at any time?	This should include type of product, such as Fresh Frozen Plasma (FFP), Platelet, Cryoprecipitate, or Immunoglobulin as these are human derived products. The reason for the transfusion should also be obtained as this may provide significant medical history. Establish in which country the transfusion occurred as donor screening policies vary by date and country and this information is helpful. Transfusions have been known to transmit bacterial, viral, protozoal and prion infections, such as variant CJD. Testing of blood donors for markers of infection varies by country and by date, so level of risk will also vary.	Any transfusions should be noted and the laboratory completing the microbiology testing should be informed if the potential donor received any transfusions within the last 3 months. Antibodies can be acquired passively through transfusions so a positive antibody test in a post transfusion sample may need to be interpreted accordingly. The laboratory interpretation must take this into account and the information should be passed on to the transfusion sample biotony should	As Organ Donation.
	transfusions if known.	be explored as part of the review of medical records and importantly the prescription chart for the current admission (NB if a potential donor has had more than one admission	



		within the 3 days prior to the current, then prescription charts for these admissions should also be reviewed).Documenting all transfusions (not just the ones relevant for haemodilution calculation) would give a full picture should there ever be the need to investigate a potential transfusion transmitted infection.	
Question	Reason for asking the Question	Additional Action to take re Organ Donation	Additional Action to take re Tissue Donation
17. Did your relative suffer from any type of brain disease such as Parkinson or Alzheimer disease or dementia?	Neurological disease may be of infectious or non-infectious origin or a neurodegenerative condition of unknown aetiology e.g. Parkinson disease or Alzheimer disease.	Not applicable to organ donation.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated.

# INF947/9 – Rationale Document for Medical and Social History Questionnaire



18. (A-D) Did your relative suffer from any one or more of the following problems: memory problems or confusion, change in personality or behaviour, or were they unsteady on their feet?	CNS conditions have a range of underlying pathologies, and for the purposes of organ and tissue donation it is important to identify and exclude those that might be of infectious origin or of unknown aetiology such as neurodegenerative conditions (e.g. Parkinson disease or Alzheimer disease). As relevant CNS conditions are not necessarily always fully diagnosed at time of death, it is important to identify potentially relevant clinical signs and symptoms as possible indicators of relevant disease processes.	Not applicable to organ donation.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated.
	Slowly progressive neurological symptoms, including paraparesis, may have a yet undiagnosed viral aetiology (e.g. HTLV).		
	New symptoms such as behavioural changes, confusion with or without fever and other symptoms, may be part of a yet undiagnosed infectious CNS process.		
	It is important to establish time of onset, duration, severity, and trend of neurological and psychiatric symptoms in order to assess their relevance. For example, patients with sporadic CJD would be expected to deteriorate noticeably from month to month. Being unable to live independently is a good indication of severity of any neurological condition, e.g. a patient with dementia is usually unable to live on their own.		
	Clinical assessment will exclude other relevant underlying conditions that may also be present beside the primary cause of death (e.g. altered behaviour of new onset, which may be infectious in origin, followed by a fall or RTA). The cause of death may not be a deferral for donation, however the underlying, as yet undiagnosed condition, may have led to the incident leading to death.		

Question	Reason for asking the Question	Additional Action to take re Organ Donation	Additional Action to take re Tissue Donation
19. Did your relative have a family history of prion disease, such as CJD, or were they ever told that they were at risk of prion disease?	Individuals at familial risk of prion-associated disease are those who have two or more blood relatives with a prion-associated disease or where the family has been informed, they are at risk following genetic testing and counselling. These patients are at increased risk of prion disease transmission.	Assessment must be made on a case by case basis and expert advice sought where necessary. 'At risk' and familial history is not an absolute contraindication to organ donation. Refer to <b>POL188</b> (Contraindications to Organ Donation).	If answer yes, patient is contraindication for tissue donation. If the donor has had genetic testing and been found not to be as risk for prion disease – accept.
20. Did your relative ever receive human pituitary extracts, e.g. growth hormones or fertility treatment or test injections for hormone imbalance?	Human Pituitary extracts have been known to have been contaminated and have led to the transmission of CJD. They have not been used in the UK since 1985, however it is uncertain when their use was stopped in other countries. Metrodin HP was an infertility treatment used up to 2003. However, patients treated after 2003 will not have been treated with this. Metrodin HP was manufactured from urine sourced in Italy and therefore was a risk of CJD. Donated eggs are classed as tissue donation due to the risk of CJD transmission.	Document information clearly to alert accepting surgeons.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated.
21. Did your relative ever have any significant infection?	Significant infections can be regarded as any infection where an individual has required investigations, hospitalisation, or a specialist referral. Infections identified in this section may be transmittable during transplantation depending on the detail. Therefore, it is important to ascertain diagnosis, treatments, and dates.	Refer to POL188 (Contraindications to Organ Donation). Initiate discussions at early stages, as appropriate.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated.
22. Did your relative come into contact with an individual with an infectious disease within the last month?	Potential donors who have been in recent contact with an infectious disease may be in the asymptomatic stage of an infection at the time of donation. It is also helpful to know what type of contact the patient had.	Initiate discussions at early stages, as appropriate.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated.
23. Did your relative have any signs of infection, e.g. colds, flu, fever, night sweats, swollen glands, diarrhoea, vomiting or skin rash within the last month?	Answers to this question will add to the clinical picture. It is important to enquire as to any treatment given, investigations, duration of illness. Further investigations may be required.	Initiate discussions at early stages, as appropriate.	Night sweats may be secondary to menopausal symptoms – having this information documented is important as this night sweats allows the tissue to be released.
24. Did your relative have any immunisations within the last 2 months?	Immunisations with live vaccine may cause severe illness in people who are immunosuppressed. By eight weeks any infection caused by the immunisation should have been controlled and so should not be passed on through donated organs or tissues. Very recent vaccination with HBV vaccine for instance (7 days) can give positive result for HBsAg during screening, which does not mean infection. (No other vaccines affect the result of routine donor characterisation	Laboratory completing the donor microbiological screen must be informed if recent HBV vaccination. Please note that infant 6-in-1 vaccine also includes Hepatitis B.	As Organ Donation.



	tests). Asking for type of flu vaccination i.e. injection versus nasal spray will help confirm whether the vaccination used was inactivated or a live vaccine List of common live and inactivated vaccines should be checked at: http://www.transfusionguidelines.org/dsg/ctd/appendicies/appendix-4-table-of- immunizations		
Question	Reason for asking the Question	Additional Action to take re Organ Donation	Additional Action to take re Tissue Donation
25. Did your relative have tattooing, body piercing, Botox injections, acupuncture, colonic irrigation, faecal transplantation, or any other cosmetic treatments or injuries that involve piercing the skin in the last 3 months?	Any piercing of the skin for these reasons may carry a risk of viral disease transmission depending on the standards of practice. It is important to confirm when and where the treatment has been carried out i.e. in the UK or not, and whether in licensed premises or not. If carried out in certain establishments, i.e. NHS or otherwise licensed establishments, tissue donation will be possible. During the 3-month period, if infection has occurred, it may not be detected by serological tests (window period). Colonic Irrigation may be unregulated if not on NHS, as such there may be an increased risk of rectal mucosa damage and infection. Faecal Microbiota – this is one of a number of treatments that can be done through the NHS or non-NHS – it is human derived and so risk of blood borne virus. Microblading and Micro needling – these procedures have become more popular in recent years and involve piercing of the skin. Unclear of licensing requirements of people who carry out these procedures. Consideration must be given to all cosmetic procedures which may pierce the skin	Document information clearly to alert accepting surgeons. Include relevant information in the virology request form to aid interpretation of results.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated depending on where and when this happened. If faecal microbiota is carried out in the NHS or by a registered professional so we know the donor is being screened and tested then accept the donor; if done outside the NHS/not by a registered professional then defer if the treatment was in the last 3 months – if more than 3 months ago accept. If the donor or donor family state that tattoo/body piercing etc was done in a high street shop, we assume the shop is abiding by the law and is therefore licensed – there is no need to look for further evidence as to whether the shop was licensed or not.



Question	Reason for asking the Question	Additional Action to take re Organ Donation	Additional Action to take re Tissue Donation
26. In the last 12 months has your relative been bitten or scratched by any animal (strays, pets, wild, farm or ticks) or been bitten by a human. Or, has your relative ever been bitten or in close contact with bats anywhere in the world or been bitten by a mammal outside the UK?	<ul> <li>Exposure to animal secretions (e.g. bites or exposure to saliva through broken skin) may result in infections, for example rabies. In the UK the risk of rabies comes from contact with infected bats. Outside the UK, bites, and scratches from infected mammals, (most commonly dogs and cats but any mammal can get infected – see below), can be a source of rabies in endemic countries.</li> <li>A potential exposure to rabies is significant at any time, so if the patient's family mentions a significant exposure, obtain information regardless of time elapsed. Close contact with animals, including domestic family pets, may lead to zoonotic infections (infections transmitted between animals and humans), which may then be transmitted through transplantation. A significant number of families will have family pets. The main risk is if the donor has been bitten by an animal or there has been unusual contact between an animal (particularly if unwell) and the donor.</li> <li>Exposure to bats:</li> <li>In the UK, bat handlers are encouraged to receive rabies vaccination. Exposure is regarded as direct contact of bat saliva or neuronal tissue with broken skin or mucosa. If a bat is found in the room of a sleeping, previously sleeping, or intoxicated person or child this is classed as exposure as the person may not be aware, they have been bitten and bites may not be visible. Otherwise, just being close to a bat does not constitute an exposure.</li> <li>Exposure to terrestrial (predominantly land living) mammals: Knowledge of any transdermal bite or scratch, lick to broken skin, contact of saliva with mucous membranes requires further discussion. Examples of animals known to have transmitted rabies: racoons, foxes, monkeys.</li> <li>Transmission of rabies through transplantation has been described when diagnosis of rabies in the donor had been missed despite presence of compatible signs and symptoms at the time of death.</li> <li>Tick bites can transfer infections, e.g. the agents that cause Lyme's disease, tick borne enc</li></ul>	If the answer to this question is yes, as much information as possible must be ascertained. Important questions to ask include: Place of incident (country, region, area). Type of animal (raccoon, skunk, fox, etc). What was the injury (bite, scratch, lick to broken skin, mucosal exposure to saliva?) When did it happen? Was the animal vaccinated against rabies? Was the animal observed by anyone in the 14 days following the incident (animals with active rabies would die within 2 weeks)? Circumstances of incident - e.g. Was the bat dead or alive? Was the dog bite provoked or unprovoked? Was it directly on bare, broken, or unbroken skin? Was any medical advice sought afterwards? Any treatment? (e.g. Rabies hyperimmunoglobulin and rabies vaccine). Would anyone else have further information or have witnessed the incident?	Tissue donation is contraindicated if the patient has ever been bitten by a non-human primate, has any animal bite where the wound is infection or not healed, or if it is less than 12 months since being bitten anywhere in the world by any mammal outside the British Isles. Refer to current TDSG-DD.

### TRAVEL RISK ASSESSMENT

This group of questions is designed to establish the risks of a potential donor having/being at risk of an infection which is not endemic within the UK. Due to the evolving patterns of infections worldwide, when a detailed travel history has been obtained it is necessary to consult both the TDSG-DD (link above) and the Geographical Disease Risk Index (GDRI) (http://www.transfusionguidelines.org.uk/dsg/gdri) for up to date information on the risk assessment criteria. It is the responsibility of the specialist nursing staff to gather appropriate information, including date, duration of travel, destination and purpose of trip; and whether the donor was well or unwell during their travel and on returning to the UK – the travel associated risk may vary by region with some countries e.g. malaria risk only in some parts of Turkey or Zika risk in the USA. It is important to get as much information as possible; document and communicate to transplant centres.

Question	Reason for asking the Question	Additional Action to take re Organ	Additional Action to take re
		Donation	Tissue Donation
27. Did your relative ever travel or live outside the UK (including business trips)?	Certain infections are distributed geographically, and the risk of exposure will depend on the length of time and activities performed in the area. For some infections, risk is highest for residents of endemic areas (e.g. Malaria and Chagas), regardless of how long ago they have left the area. Individuals who have lived in malaria affected areas, particularly from early age, may develop a partial immunity to malaria through repeated exposure; they very often have no symptoms, despite infection being present. The malaria antibody screening test will identify that the donor had infection at some point; a NAT test will identify detectable parasite in the blood at the time of donation. In general terms, most risk of tropical acute infections such as Dengue, Chikungunya and Zika exists during the 4 weeks after return from endemic areas hence dates of recent travel are important part of the risk assessment.	Due to continual changing guidance in relation to this aspect refer to current GDRI. Document if any additional tests are being processed. Initiate discussions at early stages, as appropriate.	Due to continual changing guidance in relation to this aspect refer to current TDSG-DD and GDRI.
28. In the last 12 months, did your relative travel to outside of the UK (including business trips)?	Any travel within 12 months may trigger further investigations for potential diseases such as malaria. Certain infections are distributed geographically, and the risk of exposure will depend on the length of time and activities performed in the area. Full details are important including area, dates, duration, nature of visit, type of activities.	Due to continual changing guidance in relation to travel refer to current GDRI. Document if any additional tests are being processed. Initiate discussions at early stages, as appropriate.	Due to continual changing guidance in relation to this aspect refer to current TDSG-DD and GDRI.
29. Did your relative ever have malaria or an unexplained fever which they could have picked up whilst abroad?	Malaria and other endemic infections such as West Nile Virus and T. cruzi can be transmitted by blood, organs, tissues, and cells. Full details are required, including date and duration of visit, and any treatments or investigations undertaken. If a donor was born or has lived in a malarious area for more than 6 months at any time of life, a validated anti-malarial antibody test should be performed	Due to continual changing guidance in relation to this aspect refer to current GDRI. Document if any additional tests are being processed. A validated anti-malarial antibody test should be performed	Due to continual changing guidance in relation to this aspect refer to current TDSG-DD and GDRI. A validated anti-malarial antibody test should be performed
30. Was your relative unwell whilst abroad or in the first month on their return to the UK?	If patient was unwell while abroad or within 1 month of returning to the UK the infection may have been contracted while abroad – depending on the country visited this may include infections that would require additional tests to be processed, or would contra-indicate tissue donation e.g. malaria, Zika, West Nile Virus etc. History of relevant epidemiology and symptoms are important, and an individual risk assessment needs to be initiated as early as possible to enable appropriate discussions and any testing, if required.	Depending on country visited check GDRI to see what infection risk if any is linked with that country/region of country and decide whether additional tests are required e.g. malaria testing and discuss with transplant surgeons and document.	Due to continual changing guidance in relation to this aspect refer to current TDSG-DD and GDRI.

Question	Reason for asking the Question	Additional Action to take re Organ	Additional Action to take re
		Donation	lissue Donation
31. Did your relative ever live or travel outside the UK for a continuous period of 6 months or more?	Certain infections are distributed geographically, and the risk of exposure will depend on the length of time and activities performed in the area. For some infections, risk is highest for residents of endemic areas, regardless of how long ago they have left the area. Individuals who have lived in a malaria affected areas, particularly from early age, may develop a partial immunity to malaria through repeated exposure; they very often have no symptoms, despite infection being present.	Due to continual changing guidance in relation to this aspect refer to current GDRI. Document if any additional tests are being processed.	Due to continual changing guidance in relation to this aspect refer to current TDSG-DD and GDRI.
32. Did your relative ever go to Central America, Mexico, or South America for a continuous period of 1 month or more?	Individuals who have ever been in certain areas such as impoverished, rural communities (refer to SaBTO guidelines) of Central America, Mexico, or South America for a period of 4 weeks or more may be at risk of T.Cruzi infection. Full details are important including area, dates, duration, nature of visit, type of activities.	Due to continual changing guidance in relation to this aspect refer to current GDRI. Document if any additional tests are being processed.	Due to continual changing guidance in relation to this aspect refer to current TDSG-DD and GDRI.
	For those who were born, or who have lived for a prolonged time or whose mothers were born in endemic areas for Chagas disease, family history or own history of cardiac (e.g. arrhythmia) or Gastrointestinal abnormalities are significant and should be noted.	<ul> <li>T. Cruzi antibody screening should be undertaken in donors that meet any of the following criteria:</li> <li>Born in Latin America (South America, Central America or Mexico).</li> <li>Received blood components or products while resident in Latin America (South America, Central America or Mexico).</li> <li>- Lived in rural subsistence farming communities for a continuous period of 4 weeks or more in in Latin America (South America, Central America or Mexico).</li> </ul>	<ul> <li>T. Cruzi antibody screening should be undertaken in donors that meet any of the following criteria:</li> <li>Born in Latin America (South America, Central America or Mexico).</li> <li>Received blood components or products while resident in Latin America (South America, Central America or Mexico).</li> <li>- Lived in rural subsistence farming communities for a continuous period of 4 weeks or more in in Latin America (South America, Central America or Mexico).</li> </ul>
33. Was your relative's mother born in Central America, Mexico, or South America?	T.Cruzi infection can be passed vertically from mother to child so that a child born outside this area and who has never travelled to this area is still at risk of infection if their mother was born within the stated areas.	Document if any additional tests are being processed. <i>T. Cruzi antibody screening should be undertaken in Individuals whose mothers were born in in Latin America (South America, Central America or Mexico).</i>	Due to continual changing guidance in relation to this aspect refer to current TDSG-DD and GDRI. <i>T. Cruzi antibody screening should be undertaken in Individuals whose mothers were born in in Latin America</i> (South America, Central America or



BEHAVIOURAL RISK ASSESSMENT To the best of your knowledge did your relative			
Question	Reason for asking the Question	Additional Action to take re Organ Donation	Additional Action to take re Tissue Donation
34. a Consume alcohol?	The effect of alcohol can impact on the quality of liver tissue. If yes, it is important to obtain as much information as possible. How much did the patient drink per day? What they drank (e.g. beer, spirits, wine etc)?	Document information clearly to alert accepting surgeons. E, W and N.I. – excess alcohol consumption alone is not an indication for BBV NAT testing	
34. b Smoke tobacco or any other substances?	Smoking in a donor is established to reduce both early and late survival after lung transplant. Current smoking is worse than past smoking.	Document information clearly to alert accepting surgeons.	
	There is also a relation with extent of smoking history – i.e. pack-year totals, although this is less clearly defined.	E, W and N.I. – cannabis use and/or tobacco consumption is not an indication for BBV NAT testing	
	It is likely, by analogy to the decrease in cancer risk, that not smoking for more than 10 years largely equates to being a non-smoker, although there may already be structural damage to the lungs.		
	If yes, it is important to obtain as much information as possible. How much did the patient smoke, what did they smoke and if they stopped smoking, when did they stop?		
	Donor age, for lungs otherwise acceptable, does not appear to affect outcome until the donor is >65, and even then, the effect is small. The effect of advanced age is much less than the effect of smoking. As a result, it is now recognised that lifetime non-smokers, or those who have stopped for more than 10 years, are able to donate lungs up to the age of 75.		
	Evidence suggests that E-cigarettes (such as vapers) are not harmful to lung tissue.		
	Other Substances – Looking for evidence of precarious/risky behaviours if the patient is taking a substance that cannot be obtained legally.		
34. c Take any recreational drugs?	Looking for evidence of precarious/ risky behaviours particularly if the patient is taking a substance that cannot be obtained legally.	Document information clearly to alert accepting surgeons.	Evidence of a potentially precarious/ risky lifestyle – if only smoking cannabis accept, if injected illegal drugs in the last 12 months defer, if taking other oral recreational drugs would need a risk assessment.



Question	Reason for asking the Question	Additional Action to take re Organ Donation	Additional Action to take re Tissue Donation	
Based on information obtained from blood donors who tested positive and epidemiological data from larger populations, it is known that certain groups of people may be at increased risk of infection by HIV, HCV, HTLV and HBV. Unfortunately, it is not possible to exclude all cases of infection by relying on blood testing alone as infected donors may not be identified in the very early stages of infection, commonly referred to as the 'window period'. This refers to the period between being infected and the appropriate test being able to detect the infection. It takes several days/weeks for an infected individual to start forming antibodies, and a number of weeks before the antibody levels are high enough to be detected by using an antibody detection test, however tests that are based on antigen detection will identify the infection. It is particularly important to note recent risks; whilst established blood borne infections will be detected through screening, very recent ones may not. Information must be passed on to the testing laboratory and transplant centres.				
the following apply to your relative: Was, or may have been infected with HIV, hepatitis or HTLV?		Donation). If yes, provide dates in additional box	donation is contraindicated.	
35. b Within the last 12 months have they, injected or been injected with non- prescribed drugs, including performance enhancing drugs or injectable tanning agents?	Individuals with a history of intravenous drug use remain the largest group diagnosed with HCV infection in the UK. They also have a higher rate of HIV and HBV infection. Ascertain if there was frequent exposure and dates of any exposure. Injectable tanning agents are illegal, and their manufacture is not controlled.	Document information clearly to alert accepting surgeons. If yes, provide dates in additional box	Carry out risk assessment depending on the details provided. If yes, provide dates in additional box	
35. c Been in prison or a juvenile detention centre for more than 3 consecutive days in the last 12 months? <u>NB:</u> This excludes those who have been in a police cell for <96 hours.	Individuals in prison are at a higher risk of being exposed to transmissible viruses through sexual contact and intravenous drug abuse. Ascertain details of dates and duration.	Document information clearly to alert accepting surgeons. If yes, provide dates in additional box	If yes to this question tissue donation is contraindicated.	
35 d. Taken medication to prevent HIV infection e.g. (PrEP/ pre/post exposure prophylaxis)?	There is the potential for a significantly reduced antibody response to HIV in an HIV infected individual taking PrEP - a low titre infection (being treated) or a lower, blunted antibody response will mean that the HIV infection may be missed with current testing methods. This information must be passed to the testing laboratory and discussed at early stages as modification of the testing algorithm may be required.	This information must be passed to the testing laboratory and discussed at early stages as modification of the testing algorithm may be required. If yes, provide dates in additional box	As Organ Donation. If yes, provide dates in additional box	

Question	Reason for asking the Question	Additional Action to take re Organ	Additional Action to take re
		Donation	Tissue Donation
<ol> <li>Has your relative ever had sex – consensual or otherwise? If yes, it is possible that your relative has:</li> </ol>	This question needs to be asked of all donors irrespective of age. This includes the mother of neonates.	Document information clearly to alert accepting surgeons.	
36. a Was given payment for sex with money or drugs in the last 3 months?	Individuals who receive payment for sex are at a higher risk of contracting HIV/HBV/HCV and other sexually transmitted diseases. The increased risk could be related to the high number of sexual partners, the potential promiscuity of these partners and possible drug related habits.	Document information clearly to alert accepting surgeons.	If yes to this question tissue donation is contraindicated.
36. b Ever had a sexually transmitted infection?	If the answer is yes, ascertain type of infection, treatment, and dates and where treated. Untreated STIs may eventually cause damage to many organs and tissues or could be transmitted to the recipient.	Document information clearly to alert accepting surgeons.	Acceptance criteria are specific for each condition, refer to current TDSG- DD.
36. c Ever had a sex with anyone who was diagnosed with a Viral Haemorrhagic Fever (VHF)	There is evidence of persistent virus in individuals who recover from several forms of VHF. Based on this advice, permanent exclusion has been introduced for donors who have had sex with an individual who had been diagnosed with VHF If the answer is yes, ascertain type of infection, treatment, and dates and where treated. Untreated STIs may eventually cause damage to many organs and tissues or could be transmitted to the recipient.	Document information clearly to alert accepting surgeons.	If yes to this question tissue donation is contraindicated.
37. Did your relative have sex, consensual or otherwise in the last 3 months? If yes, is it possible that in the last 3 months your relative had sex with:		Document information clearly to alert accepting surgeons.	
37. a (for male patients only) another man?	Men who have sex with men have a much higher prevalence of HIV infection and other sexually transmitted diseases.	Document information clearly to alert accepting surgeons.	If yes to this question tissue donation is contraindicated.
37. b (for female patients only) a man who has ever had sex with another man?	The sexual partners of individuals who fall into the above category (37a) are at higher risk of HIV infection and other sexually transmitted diseases.	Document information clearly to alert accepting surgeons.	If yes to this question tissue donation is contraindicated.

## INF947/9 – Rationale Document for Medical and Social History Questionnaire



Question Reason for asking the Question Additional Action to take re Organ Additional Action to take re Donation **Tissue Donation** Document information clearly to alert Other than Q37i (see below) - If 37. c Anyone who is HIV or Transmission of blood borne sexually transmitted diseases is higher in individuals HTLV positive? who fall into these categories. accepting surgeons. yes to any of these questions tissue donation is contraindicated. 37. d Anyone who has hepatitis? 37. e Anyone who had a sexually transmitted disease? 37. f Anyone who has ever been given payment for sex with money or drugs? 37. g Anyone who in the last 12 months has injected, or been injected, with non-prescription drugs, including performance enhancing drugs or injectable tanning agents. 37.h Anyone who could have had sex, in any part of the world, where AIDS/HIV is very common (this includes most countries in There is a higher risk of contracting some sexually transmitted infections in some If the donor has had sexual contact Africa)? parts of the world where they are more common. with anyone with a diagnosed infection in the previous 6 months 37.i Anyone who has e.g. Zika then there needs to be a developed an illness risk assessment - when was the related to travel such as infection/sexual contact, can we test. Zika? do we need to defer or can we accept based on the type of tissue. 38. Having answered all the The highest ranking/nearest relative may not be the person with the most relevant and current information to answer questions of a sensitive nature about the donor. If the answer is "yes" to this question, every effort should be made to identify and contact that individual to get the relevant information from that person as well. previous questions, is there anyone else who you think may provide more information?