Objective

The document informs and guides the SN in requesting the relevant blood tests during donor characterisation and the surgical process, ensuring the result are reported.

Changes in this version

Section 4 Reference to volume required for Additional Blood Testing.
Section 5 Addition of requirement to document in the visible section of DonorPath if any additional microbiology testing triggered.
New section 9.
Additional requirement of maternal blood samples

Roles

Specialist Nurses (SN)

- Where reference is made in this document to SN (Specialist Nurse), this term includes SNOD (Specialist Nurse - Organ Donation), SR (Specialist Requestor), SNFC (Specialist Nurse - Family Care).
- To ensure that the required blood tests are carried out, entered onto the DonorPath application and reported on.
- To report and communicate the results to Hub Operations/Recipient Centre Points of Contacts (RCPoCs) / Tissue Establishments (TEs).
- To identify actions and interventions required for abnormal results.
- To facilitate any additional testing as requested by the RCPoCs.

Recipient Centre Points of Contact (RCPoC)

- To receive the blood test results via EOS or EOS Mobile/email/verbally.
- To relay the information to the implanting surgeons.
- To arrange transport for additional samples requested from the donor hospital.

Restrictions

- This SOP is to be utilised by qualified and trained SN. In the event of a SN who is in training, this SOP is to be utilised under supervision.
- Any interventions, treatments or restrictions for a potential DCD must be discussed and agreed with the treating clinician.

Items Required

- None

Instructions

Initial Donor Assessment

1. Routine blood results including: Group & Save, FBC, U&Es, LFTs, Amylase, HbA1c and clotting screen

Blood Group

1.1 Only use a Blood Group that has been confirmed by serological testing.

1.2 Obtain paper copy of the blood group and check against patients' ID band to confirm name, date of birth, and NHS number/hospital number / CHI number (Scotland). This must be witnessed by a qualified health care professional (HCP).

1.3 Blood group must be confirmed against 3 PID. The SN and HCP must sign, print name, date and time on the paper copy prior to registering patient with Hub Operations. This paper copy must be used to confirm blood group with Hub as per DAT3734.

Additional routine bloods

1.4 Request full set of routine blood results (if >12 hours old).

1.5 Review the results, including the trends and discuss any abnormal results with the medical practitioner caring for the patient.

1.6 Identify any actions/interventions if required for abnormal results.

1.7 Document the results on DonorPath and communicate to Hub Operations & RCPoC(s) if required. Ensure that the RCPoC(s) are aware of any actions/interventions for abnormal results.

1.8 Request repeat testing or additional testing as requested by the RCPoC(s).

1.9 Voice record clinical conversations, documenting the time and date they occur on DonorPath or **FRM4212** in line with **SOP3649**.

1.10 In the case of DonorPath, EOS or IT failure complete **FRM4212, FRM4211, FRM4193** as stipulated in **SOP3925**.

2. Arterial Blood Gases (ABGs)

2.1 Review previous ABGs, including any ABGs performed during the neurological death testing.

2.2 For CT offering the ideal standard for CT centres assessment is a reference gas on ventilator settings of: FiO2 100%, PEEP 5 (a PEEP up to +8 would be acceptable). ABG should be obtained 20 minutes after ventilatory adjustments. If this is not able to be performed, for example due to clinical condition of the patient and following discussion with the clinical team, document detail on DonorPath.

2.3 Return to baseline settings, or agree requirements with clinical team, following completion. If the donating unit have a requirement for undertaking the reference ABG in a different way please follow local protocols and document on DonorPath, for communication with RcPOC(s).

2.4 During the offering process 2 hourly 100% ABGs will be required as per DAT3734.

2.5 Review results, discuss any abnormal results with the medical practitioner caring for the patient and identify actions/interventions required.

2.6 Document the results on DonorPath and communicate to the relevant RCPoC(s). Ensure that the RCPoC(s) are aware of any actions/interventions for abnormal results.

2.7 Request any additional ABGs as required by the RCPoC(s).

2.8 Voice record clinical conversations and document the time and date they occur on DonorPath or **FRM4212** in line with **SOP3649**.

Essential Donor Characterisation

3. Pregnancy β-HCG blood test

3.1 Patients with reproductive capacity between the ages of 12 and 55 years (before their 56th birthday) should be considered as patients who could potentially be pregnant.

3.2 Establishing pregnancy status is mandatory and a β-HCG blood test is required to exclude pregnancy (unless the individual is already known to be pregnant or documented total abdominal hysterectomy with bilateral salpingo-oopherectomy). A urine sample is not acceptable, in line with recommendation from National Organ Donation committee.

3.3 As part of the donor characterisation process, SN should confirm with the relevant HCP whether a β-HCG blood test has already been performed on the patient during this admission to hospital.

3.4 If β-HCG blood test has not been performed during current admission the SN must inform the next of kin/nearest relative/partner that for donation to proceed and as part of routine donor assessment a blood test will be required to exclude pregnancy.

3.5 The local hospital is the default laboratory for performing the ß-HCG blood test. If there are difficulties accessing a β-HCG blood test, engage with local key stakeholders and laboratory staff to seek options for processing including transfer to alternative local laboratory if required. Refer to Establishing Pregnancy Status and Pregnancy in Donation **MPD891**.

4. Microbiology, Tissue Typing and Additional Blood Testing

Blood sample volumes

Test	Volume adult	Volume paediatric	Sample type
HLA	6mls	3mls	EDTA
Microbiology	14mls	Agree volume with lab proportionate to age/size	Clotted
Additional Blood Testing* (see Sections 5-9)	14mls	Agree volume with lab proportionate to age/size Paed <30kgs minimum sample of 2mls blood in EDTA	EDTA

*Where maternal microbiology is required a further sample to accompany any tissue donation should be taken prior to retrieval in line with JPAC guidelines.
These blood volumes have been agreed with ALL laboratories in UK

Area	Potential Donor	Bloods for HLA	Bloods for Microbiology
England, Wales & NI	Criteria met for deemed (Not registered a decision) Opted Out	Cannot be taken without discussion & agreement from family.	Cannot be taken without discussion & agreement from family or as part of completion of consent.
	Expressed decision On ODR Family expressed decision	May be taken and processed.	May be taken and sent but testing must not commence without discussion and agreement from the family or as part of completion of consent.
Scotland	DBD donors – confirmatory DDNC testing has been carried out.	Cannot be taken without discussion & authorisation from family until after duty to inquire and checking for unwillingness or change of mind.	Cannot be taken without discussion & authorisation from family until after duty to inquire and checking for unwillingness or change of mind.
	DCD donors – or prior to DDNC testing	Cannot be taken without discussion & authorisation (for donation & Type A PDPs) from family until after duty to inquire and checking for unwillingness or change of mind.	Cannot be taken without discussion & authorisation (for donation & Type A PDPs) from family until after duty to inquire and checking for unwillingness or change of mind.

4.1 Consider impact of transfusions/haemodilution on samples – see section 10.

4.2 Inform the relevant laboratory staff that samples are being sent and provide details of the potential donor and an estimated time of arrival of the samples.

4.3 Confirm the contact details for the laboratory staff.

4.4 Fill bottles as per manufacturers guidance to FILL line (see volumes above).

4.5 Collection of samples and labelling must be performed as one uninterrupted process.

4.6 Blood taken must always be labelled at the bedside by the HCP (SN or bedside nurse) who has taken the sample. Sample tubes must never be pre-labelled.

4.7 All handwritten labels must be legible with **at least three types of patient identifiers** and include date, time and location (i.e. hospital) the sample was taken. If used, pre-printed labels must adhere to hospital and laboratory requirements.

4.8 If a pre-transfusion sample is required, ensure that the Coroner/Procurator Fiscal's permission has been sought if applicable – refer to **MPD865**. Ensure sufficient samples remain should Coroner/Procurator Fiscal require. Ensure date, time and location (i.e. hospital) the sample was taken is clearly written on the sample tube.

4.9 All specimens, including maternal samples, MUST be clearly and unequivocally identified with a minimum of three key identifiers which must be cross-checked to positively identify that the information on the sample matches the patient and the information given on the request form prior to packaging and sending.

4.10 Complete **FRM4278** and **FRM4279** and package the blood samples, including maternal samples if applicable, using the bio-pouch, with the correlating form. If a donor number has not yet been generated, ensure the DonorPath referral ID and a minimum of 3 points of PID including the donors name are used.

4.11 **Breast feeding and maternal samples**: For patients under 18 months and any child who has been breast-fed in the last 12 months, microbiological samples, including a sample to accompany tissue donation if applicable, will be required for testing from the child's mother or individual who breast fed the child as per the Medical and Social History (MaSH) rationale document **INF947**. These maternal samples must be labelled with at least 3 PID and include date, time and location (i.e. hospital) the sample was taken. These 3 maternal PID must be recorded on DonorPath and provided on all documentation including DCFS handover **FR5499**.

4.12 On receipt of microbiology results follow steps in **SOP4618** and enter results directly onto DonorPath or, in the event of IT failure **FRM4212. Scotland only**: email copy of **FRM1538** to SNBTS at NSS.SNBTS-Tissues-Seniors@nhs.scot.

4.13 Check results entered onto DonorPath for accuracy.

Additional Blood Testing (characterisation)

Note: any additional blood testing triggered as part of donor characterisation must be documented in the visible section of DonorPath this can be seen by Recipient Centres.

5. HEV Testing

5.1 For every donor in E, W, NI collect single additional EDTA sample for HEV and complete **FRM5025**

- **Scotland only**: no additional sample is required for HEV

6. BBV NAT Testing

6.1 Obtain travel history and check Geographical Disease Risk Index (GDRI) for ALL travel outside of UK. Be cautious - the website is frequently updated to reflect as the prevalence of diseases change. Record all history and details (including areas visited and dates of travel) within DonorPath and on **FRM5025** or **FRM5814** (Scotland).

6.2 E,W,NI - If high risk factors are identified during the behavioural risk and sexual history assessment (excluding alcohol and tobacco consumption) then BBV NAT testing is indicated. Refer to MaSH rationale document **INF947** and **FRM4211** (if questions 34 C – 37 A, B, C, D, E, F, G to H are answered yes proceed with testing samples). Ensure the reason for testing is communicated to MSL Virology either on the referral form or by email.

6.3 reason for testing is communicated to MSL Virology either on the referral form or by email.

6.4 E,W,NI - In circumstances of positive virology during characterisation or donation process but BBV NAT testing has not been triggered then SN must notify MSL Virology via e-mail to process BBV NAT testing on HEV sample.

6.5 In either scenario additional sample is not required.

6.6 Scotland – BBV NAT testing is performed routinely on all donors. Complete FRM5814 and send together with packaged blood samples, to SNBTS.

7. Malaria and Trypanosoma Cruzi (T.Cruzi) testing

7.1 Completion of MaSH Questionnaire and/or information from the medical notes or GP history may indicate that the patient could be at potential risk of Malaria and/or T.Cruzi (refer to **INF947** Rationale Document for MaSH).

7.2 Due to continual changing guidance in relation to Malaria and T.Cruzi refer to the GDRI for advice regarding additional testing. A GDRI search is required in every country visited to eliminate the need to test.

7.3 E,W,NI - If Malaria and T.Cruzi testing indicated complete FRM5025. Scotland - If Malaria and T.Cruzi testing indicated complete FRM5814. Ensure the reason for testing is communicated to MSL Virology either on the referral form or by e-mail.

8. West Nile Virus testing

8.1 Completion of MaSH Questionnaire with the family and/or information from the medical notes or GP history may indicate that the patient may be at potential risk of West Nile Virus (refer to **INF947** Rationale Document for MaSH).

8.2 Refer to GDRI for advice regarding additional testing, A GDRI search is required in every country visited to eliminate the need to test. In addition, JPAC website provides further information re: risk of exposure in defined areas and timeframes for requesting test.

8.3 Testing is indicated if travel to a high risk area has occurred (1st May to 30th November) and patient is within 28 days of return from travel.

8.4 E,W,NI - If WNV testing is indicated complete **FRM5025**. Ensure the reason for testing is communicated to MSL Virology either on the referral form or by e-mail. Scotland - If WNV testing is indicated complete **FRM5814**. Ensure the reason for testing is communicated to SNBTS on the referral form.

9. Transfusions and Haemodilution

9.1 Large volume blood loss requiring intravenous fluid replacement therapy may result in false negative screening test results due to dilution of specific antibodies or antigens below the lower limit of detection.

9.2 The volume of fluid that may be infused before false negative results may occur depends on the size of the individual, amount of blood loss and the nature of the infused fluid. If haemodilution calculation is >50%, a pre-dilution must be sought. If this sample cannot be found, then the Microbiology laboratory, RCPoC's & TE's must be informed and documented on DonorPath/FRM4211.

9.3 If the patient has been transfused with blood, blood components or plasma expanders (these include but are not limited to colloid, HAS, immunoglobulin therapy etc) in the immediate pre-donation period (within 48 hours of donation) then the sample obtained prior to transfusion should be sought and tested. If a pre-transfusion sample is not available for testing, then this must be recorded in DonorPath/FRM4211 and reported to clinicians responsible for transplantation.

9.4 If a pre-transfusion/pre-dilution blood sample is obtained for microbiology testing, then there is no requirement to send an additional post-transfusion/post-dilution sample.

9.5 However, if pre-transfusion/pre-dilution blood sample results are obtained AFTER post-transfusion/post-dilution results, both results should be included onto DonorPath to ensure that both are visible.

10. Labelling and transport of samples

10.1 Fill bottles as per manufacturers guidance to FILL line (see volumes section 4).

10.2 Collection of samples and labelling of tubes must be performed as one uninterrupted process.

10.3 Blood taken must always be labelled at the bedside by the HCP (SN or bedside nurse) who has taken the sample. Sample tubes must never be pre-labelled.

10.4 All handwritten labels must be legible with at least three PID and include date, time and location (i.e. hospital) the sample was taken. If used, pre-printed labels must adhere to hospital and laboratory requirements.

10.5 Package samples in bio-pouch for transfer.

10.6 If a donor number has not yet been generated, ensure the DonorPath referral ID and a minimum of 3 PID including the donors name are used.

10.7 Inform laboratory of pending samples, including additional samples to be forwarded on to MSL Virology/SNBTS. Ensure that any delays in obtaining and/or sending of the samples is communicated with the relevant laboratory staff.

10.8 Arrange transport of the samples to the local testing laboratories. Record estimated and actual time for collection on DonorPath.

10.9 Document conversations and actions within DonorPath.

11. Contacting the laboratories

Microbiology Services Laboratory –Virology (MSL Virology) in Colindale is the reference laboratory for England, Northern Ireland and Wales.

Scottish National Blood Transfusion Service (SNBTS) is the reference laboratory for Scotland.

In circumstances where bloods have been sent for processing and a subsequent risk factor has been identified following completion of MaSH, e-mail MSL Virology or SNBTS (Scotland).

- 3 PID (NHS number/Hospital number/CHI number, ODT number, date of birth and full name).
- Additional marker request (for example: BBV-NAT HCV-AB or Malaria).
- Rationale for the request. (for example, travel to South America for 6 months returning to the UK 2 weeks ago and history if IVDU).
- **Do NOT send a second form.**
- **Do NOT send further blood samples.**

MSL Virology:

- Email NTMRL@nhsbt.nhs.uk with following details:
- 3 PID (Including donor number)
- Advise local testing laboratory sending sample.
- Clearly state which ODST.

SNBTS:

- Telephone SNBTS **on 0131 314 5535** with following details:
  - 3 points of donor identification (Including donor number)
  - Advise local testing laboratory sending sample.
  - Confirm ODST.

In circumstances when small samples are taken for paediatric donors <30kgs the mandatory tests will be prioritised. NB: If small samples (2mls) are sent this is sufficient for HEV ONLY.

12. Reconciliation of Additional Testing Results

12.1 The DFCS receive notification via email from reference laboratory to confirm receipt of samples. DFCS will check anticipated results from the handover **FRM5499** and update visual management system.

12.2 If no result in 7 days following donation the DFCS will follow up

12.3 Refer to **SOP3579** for detail and information on actions when receiving microbiological blood results.

12.4 Results from additional testing may need to be recorded on DonorPath where there is no dedicated result field. In this scenario ensure clear documentation of receipt of results and actions performed in sequence of events and follow **SOP3579**.

13. Non-proceeding organ donors

13.1 In cases where organ donation stands down and HLA has not been completed please inform HLA laboratories to stand down and any other relevant laboratories if testing is no longer required.

13.2 If additional testing has been triggered (BBV NAT, Malaria, T.Cruzi, WNV) and patient may still donate tissue then please consider this before informing MSL Virology/SNBTS that testing is no longer required.

13.3 TEs do their own ‘routine’ microbiology screening so will not be impacted by standing down ‘routine’ microbiology.

13.4 If **FRM5499** has already been sent to DFCS then please notify DFCS that donation has stood down, so they do not pursue outstanding Microbiology results.

End of Procedure

Definitions

- ABG – Arterial Blood Gas
- BBV – Blood Borne Virus
- β-HCG – Human Chorionic Gonadotrophin
- CT – Cardiothoracic
- DBD – Donation after Brain Death
- DCD – Donation after Circulatory Death
- DDNC – Diagnosing Death using Neurological Criteria
- DFCS – Donor Family Care Service
- EDTA – ethylenediaminetetraacetic acid
- EOS – Electronic Offering System
- FBC – Full Blood Count
- FiO2 – Fraction of Inspired Oxygen
- GDRI – Geographical Disease Risk Index
- GP – General Practitioner
- HAS – Human Albumin Solution
- HCP – Health care Professional
- HEV – Hepatitis E Virus
- HHV 8 – Human Herpes Virus 8
- HLA – Human Leukocyte Antigen
- IVDU – Intravenous Drug Use
- JPAC – joint United Kingdom Blood Transfusion Services Professional Advisory Committee
- LFT – Liver Function Test
- MaSH – Medical and Social History
- MSL – Microbiology Services Laboratory
- NHS – National health Service
- NODC – National Organ Donation Committee
- ODR – Organ Donor Register
- ODST – Organ Donation services Team
- ODT – Organ Donation Transplantation
- PID – Points of Identification
- RCPoC – Regional Centre Point of Contact
- RM – Regional manager
- PNA – Ribonucleic Acid
- SARS – Severe Acute Respiratory Syndrome
- SNBTS – Scottish National Blood Transfusion Service
- SN - Specialist Nurse - this term includes SNOD (Specialist Nurse - Organ Donation), SR (Specialist Requestor), SNFC (Specialist Nurse - Family Care).
- SOP – Standard Operating Procedure
- T Cruzi – Trypanosoma CruzI
- TE – Tissue Establishment
- U&E's - Urea and Electrolytes
- WNV – West Nile Virus

Related Documents/References

- **FRM4212** - Organ Donation Clinical Pathway
- **FRM4211** - Medical and Social History Questionnaire (MaSH)
- **FRM4193** - Core Donor Data - SNOD (Used as EOS back-up)
- **SOP3925** - Manual Organ Donation Process for a Potential Organ and/or Tissue Donor in the event of DonorPath/IT network unavailability
- **FRM4278** - Virology/Microbiology Request Form
- **FRM5025** - Additional Testing Request Form
- **FRM5814** - BBV Screen/Malaria/WNV/T.Cruzi Request Form (Scotland Only)
- **MPD891** - Establishing Pregnancy Status and Pregnancy in Donation
- **FRM4279** - HLA Typing Request
- **SOP4618** - Receipt and Management of Microbiological Blood Results at the Time of Donation
- **MPD865** - Obtaining Coroner/Procurator Fiscal Decision
- **SOP3649** - Voice Recording of Organ Donor Clinical Conversations
- **INF947** - Rationale Document for Medical and Social History Questionnaire
- **FRM1538** - Authorisation – Solid Organ and Tissue Donation
- **SOP3579** - Management of Microbiological Results Received Post Organ and/or Tissue Donation
- **SOP5869** - SARS-Cov-2 Deceased Organ Donor Screening
- **DAT3734** - Registration call between ODT Hub Operations and Specialist Nurse – Organ Donation
- **FRM5499** - SN to DFCS Handover Form
- Geographical Disease Risk Index https://www.transfusionguidelines.org/dsg/gdri
- NHSBT Guidance on Handling Person Identifiable Information: http://nhsbtweb/userfiles/final%206%20IG%20proofs.pdf

Appendices

N/A