Objective

During characterisation of the patient, the document informs and guides the SNOD in requesting the relevant blood tests and ensures the result are reported

Changes in this version

Section 3 Addition of Scottish legislation changes and duty to inquire to check for unwillingness to be a donor
Name change as NTMRL now renamed as Microbiology Services Laboratory – Virology (MSL Virology). The email address for the lab remains unchanged NTMRL@nhsbt.nhs.uk
Name change as DRD is now Donor Family Care Service (DFCS)
6.1 Addition of colloids to transfusion guidelines, 6.2 Haemodilution clarification
7.1 Clarification that testing for Covid 19 SARS-CoV-2 RNA is now being performed routinely on all ODT referrals (excluding Scotland)
Splitting of section 8.1 for clarity and clarity of arrangements specific to Scotland and addition of section 8.2
For Scotland no additional sample is required for Covid 19 SARS-CoV-2 RNA testing / storage.
Clarification that additional samples are not required if high risk factors are identified
12.1 Clarity over stand down process, including HLA and TES.
Reminder to ensure that if high risk factors are identified and additional testing need to communicate this to MSL Virology on the form or via e-mail.
Clarification that when contacting MSL Virology/SNBTS via email that use minimum of 3 points of PID: NHS number, ODT number, date of birth and full name.
Consideration to continue with MSL Virology/SNBTS testing if organ donation has stood down but tissue donation still planned.
Clarification that when maternal microbiology samples are required 3 points of maternal PID must be recorded on DonorPath and provided on all documentation.
Addition that all specimens MUST be clearly and unequivocally identified with a minimum of three PID which must be cross-checked.

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

Items Required

- None

Instructions

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

1.1 Only use 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 patient's 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 and 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**.

1.4 Full set of routine blood results requested (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 the results 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 and document 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)

Any interventions, treatments or restrictions for a potential DCD must be discussed with the treating medical practitioner who holds the final decision.

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

2.2 For CT offering the ideal standard for CT centres assessment is a reference gas on ventilator settings of: 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 undertaken, for example due to clinical condition of the patient and following discussion with the clinical team and documented on DonorPath.

2.3 Return to baseline settings, or agree requirements with caring team, following completion. If the donating unit have a requirement for undertaking the reference gas 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% blood gasses 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 for abnormal results.

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 requested 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**.

3. Microbiology and Tissue Typing

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.
	Express 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 BSD testing has been carried out.	Cannot be taken without discussion & authorisation from family after duty to inquire and checking unwillingness or change of mind.	Cannot be taken without discussion & authorisation from family after duty to inquire and checking unwillingness or change of mind.
	DCD donors – or prior to BSD testing	Cannot be taken without discussion & authorisation (for donation & Type A PDPs) from family after duty to inquire and checking unwillingness or change of mind.	Cannot be taken without discussion & authorisation (for donation & Type A PDPs) from family after duty to inquire and checking unwillingness or change of mind.

****Please consider impact of transfusions/haemodilution on samples – see section 6****

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

3.2 Confirm the minimum blood volume if required - for example, for a paediatric donor.

3.3 Confirm the contact details for the laboratory staff.

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

3.5 Sample tubes must never be pre-labelled.

3.6 Blood taken must always be labelled at the bedside by the HCP (SN or bedside nurse) who has taken the sample.

3.7 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.

3.8 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.

3.9 All specimens 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.

3.10 Once cross checking confirmed complete **FRM4278** and **FRM4279** and package the blood samples with the correlating form. If a donor number is not yet generated on DonorPath a minimum of 3 points of PID including the donors name must be used.

3.11 For patients under 18 months and any child who has been breast-fed in the last 12 months, microbiological samples 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.**

3.12 These maternal samples must be labelled with at least 3 points of patient identifiers and include date, time and location (i.e. hospital) the sample was taken. These 3 points of maternal PID must be recorded on DonorPath and provided on all documentation including DCFS handover FR5499

3.13 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 to email copy of **FRM1538** to SNBTS at NSS.SNBTS-Tissues-Seniors@nhs.scot

3.14 Check results entered onto DonorPath for accuracy.

4. Pregnancy Testing

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

4.1 In all cases of organ donation, a β-HCG blood test must be performed to confirm pregnancy status, unless the individual is already known to be pregnant.

4.2 The recommendation from the National Organ Donation Committee (NODC) is that the pregnancy test result must be confirmed via a β-HCG blood test not urine pregnancy test and it is mandatory to exclude pregnancy

4.3 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.

4.4 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.

4.5 The local hospital is the default laboratory for performing the ß-HCG blood test. If there are difficulties accessing a β-HCG blood test, escalate to RM/On call RM. Refer to Establishing Pregnancy Status and Pregnancy in Donation **MPD891**.

5. Transport of samples

5.1 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.

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

5.3 Document conversations and actions within DonorPath.

6. Transfusions and Haemodilution

Large volume blood loss requiring intravenous fluid replacement therapy has the potential to lead to false negative screening test results owing to dilution of specific antibody or antigen below the lower limit of detection of the test.

If required, seek advice from the microbiologist/TM/RM.

If HM Coroner/Procurator Fiscal is involved, their permission **must** be sought before a pre-transfusion sample is accessed and sent for microbiological testing.

6.1 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 lab, RcPOC's & TES must be informed and documented on DonorPath/FRM4211

6.2 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.

6.3 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.

6.4 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.

Additional Blood Testing

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 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.

7. HEV Testing & COVID 19 SARS-CoV-2 RNA (storage)

7.1. Testing for Covid 19 SARS-CoV-2 RNA is now being performed routinely on all ODT referrals in England, Northern Ireland and Wales (E,W,NI)

7.2. For every donor in E,W,NI please continue to collect single additional EDTA sample for HEV and Covid 19 SARS-CoV-2 RNA (as per **SOP5869)** and complete **FRM5025**.

7.3. **Scotland only:** no additional sample is required for HEV or COVID 19 SARS-CoV-2 RNA testing/storage. HEV is tested routinely and COVID samples are stored as currently not tested.

8. BBV NAT Testing

8.1. 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.

8.2. In circumstances of positive virology on the night 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.

8.3. In either scenario additional sample is not required.

Scotland only: BBV NAT testing is performed routinely on all donors in Scotland. Complete **FRM5814**

Please ensure that you check the Geographical Disease Risk Index (GDRI) for all travel outside the UK as changes are frequently made to the website as the prevalence of diseases change. Please record the history and details (including areas visited and dates of travel) within DonorPath and on the referral form sent to MSL Virology as they need as much information as possible to allow for appropriate assessment with regards to testing. The JPAC website gives further information regarding the risk of exposure in the defined areas and the timeframes for requesting a WNV test. This must be referred to in conjunction with the GDRI.

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

9.1. 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 Malaria and/or T.Cruzi (refer to **INF947** Rationale Document for MaSH).

9.2. Due to continual changing guidance in relation to Malaria and T.Cruzi refer to the GDRI for advice regarding additional testing. **All** countries travelled to require a GDRI search to eliminate requirement to test.

9.3. If Malaria and T.Cruzi testing indicated complete **FRM5025**. Ensure the reason for testing is communicated to MSL Virology either on the referral form or by e-mail.

Scotland only: Complete **FRM5814**.

10. West Nile Virus testing ****

10.1. 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).

10.2. Refer to GDRI for advice regarding additional testing, all countries travelled to require a GDRI search to eliminate requirement to test.

10.3. 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.

10.4. 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.

10.5. Scotland only: **Complete FRM5814**.

11. Contacting the laboratories

11.1. 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 points of ID (NHS 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 points of donor identification (Including donor number)
- Local testing laboratory sending sample

- SNOD team

SNBTS:

- Telephone SNBTS **on 0131 314 5535** with following details:
  - 3 points of donor identification (Including donor number)
  - Local testing laboratory sending sample
  - SNOD team

12. Non-proceeding organ donors

12.1 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.

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

12.3 TES do their own 'routine' microbiology screening so will not be impacted by standing down 'routine' microbiology.

12.4 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.

13. Reconciliation of Additional Testing Results

13.1. 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.

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

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

13.3. 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**.

⊖ End of Procedure

Definitions

- None

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 Blood Testing Request Form
- **FRM5814 -** BBV Screen/Malaria/WNV/*T.Cruzi* request form (Scotland Only)
- **MPD891 -** Establishing Pregnancy Status and Pregnancy in Donation
- **FRM4279 -** National HLA Typing Request Form
- **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 -** SNOD to DFCS Handover
- 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