

**This National Operating Procedure replaces: NOP002**

**Effective: 6<sup>th</sup> December 2016**

***Summary of Significant Changes***

Document updated to reflect the changes to organ characterisation, data collection and the use of normothermic organ storage.

***Policy***

To ensure the quality and safety of organs for transplantation, and to minimise the risk of harm to transplant recipients, information must be available to permit characterisation of organ donors and donated organs.

The retrieving surgeon must verify that all required information is available before proceeding to retrieval, and also identify any further information that may be required.

The implanting surgeon must ensure that they have received all relevant information to permit donor and organ characterisation before proceeding to transplantation.

The decision to use an organ for transplant lies with the implanting surgeon based on the information available.

***Purpose***

The purpose of this document is to outline the responsibilities of

- The retrieving surgeon in the verification of patient identity, consent/authorisation and organ/donor characterisation prior to organ retrieval.
- The implanting surgeon in the verification of information received on a donated organ and donor characterisation to enable them to make an informed decision on the safety and suitability of an organ for transplantation.

Text in this document which is underlined is a mandatory requirement under the Quality and safety of organs for transplantation regulations 2012 (updated July 2014).

***Responsibilities***

**Implanting Surgeon** - To ensure they have received, and verified all relevant information to enable a decision on the safety and integrity of a donor organ before proceeding to transplantation.

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**Living Donor Coordinator** - To undertake a thorough assessment of the potential donor to ensure an accurate medical, family and social history, in conjunction with Registered Medical Practitioners (RMPs) within the transplant medical team.

**Recipient Centre Point of Contact (RPoC)** - To communicate information to the implanting surgeon for a final decision to be made on accepting an organ for transplant. To communicate requests for further information from the implanting surgeon to the SNOD or retrieving surgeons.

**Retrieving Surgeon** - To review and verify the information collated during donor assessment and to ensure relevant investigations have been performed. To undertake peri-operative assessment of the donor and donated organ/s. To ensure the RPoC and implanting surgeon are notified if an organ appears sub-optimal, or if any damage or unexpected abnormality is encountered which might compromise the function or safe use of an organ.

**Specialist Nurse Organ Donation (SNOD)** - To ensure all relevant information is communicated to the RPoC and Duty Office. To communicate all relevant information from the RPoC to the retrieving surgeon. To seek advice and guidance from the retrieving or implanting surgeon, if required.

#### ***Definitions***

**Donor characterisation** - Collection of the relevant information on the characteristics of the donor needed to evaluate their suitability for organ donation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation. For further information on the definition of relevant information see ***NOP001 v2 Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation.***

**Donor Path Application** – Electronic application used by SNODs to capture donor data to enable transplant centres to access donor data via EOS or EOS mobile.

**EOS** – Electronic Operating System.

**EOS Mobile** – Electronic Operating System mobile version.

**The EU Directive/European Union Directive** - The Directive (2010/53/EU) of the European Parliament and of the Council of 7<sup>th</sup> July 2010 (Amended 2014) on standards of quality and safety of human organs intended for transplantation.

**Implanting surgeon** - Surgeon who makes the final decision to use an organ for transplantation, also responsible for performing the transplant operation.

**Living Donor Coordinator (LDC)** - Specialist Nurse with the relevant knowledge, skills and training in living donation and transplantation.

**NHSBT** - NHS Blood and Transplant.

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**NHSBT Living Donor Scheme Co-ordinator** - Person working within the Data Executive at NHSBT who administers the NLDKSS .

**NOPs** – National Operating Procedures.

**NORS Standard** – The National Standard for Organ Retrieval from Deceased Donors.

**Organ** - Differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation. For the purposes of this procedure, an organ is considered to be intended for transplantation, and includes those tissues and cells retrieved to directly support organ transplantation e.g. accessory vessels, spleen, lymph nodes.

**Organ characterisation** - Collection of the relevant information on the characteristics of the organ needed to evaluate its suitability, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation. For further information on the definition of relevant information see ***NOP001v2 Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation***.

**Organ Donation Services Team (ODST)** - Organ Donation Services Team working within the Organ Donation and Transplantation Directorate. The Directorate is one of the three arms of NHS Blood and Transplant (NHSBT) providing support to transplantation services across the UK.

**Recipient Centre Point of Contact (RPoC)** - Healthcare professional responsible for communicating information to the implanting surgeon for a final decision to be made on accepting an organ for transplant.

**Registered Medical Practitioner (RMP)** - Medical practitioner who is registered and with a licence to practice by the General Medical Council.

**Retrieving surgeon** - Lead retrieval surgeon.

**SaBTO** - Advisory Committee on the Safety of Blood, Tissues and Organs:  
[www.dh.gov.uk/ab/SaBTO](http://www.dh.gov.uk/ab/SaBTO)

**Specialist Nurse Organ Donation (SNOD)** - Specialist Nurse with the relevant knowledge, skills and training in organ donation, working within NHSBT Organ Donation Services Teams (ODST).

**Transplant medical team** - Members of the transplant team who are medical practitioners, licensed to practice by the General Medical Council, one of whom will be the implanting surgeon.

**UK Living Kidney Sharing Scheme (UKLKSS)** -Includes paired/pooled donation, altruistic donation and altruistic donor chains.

***Applicable Documents***

The British Transplantation Society/Renal Association UK Guidelines for Living Donor Kidney Transplantation (current edition)

Directive 2010/53/EU of the European Parliament and of the Council 7 July 2010 on standards of quality and safety of human organs intended for transplantation

**FRM4121** - Kidney Donor Information (KP4)

**FRM4122** - Deceased Donor Pancreas Information (P-DEC-DI-INTERIM)

**FRM4147** - Liver Donor Information (L4)

**FRM4194** - Cardiothoracic Donor Information (C-DI)

**FRM4281** - Consent - Solid Organ and Tissue Donation (England, Northern Ireland and Wales)

**FRM1538** - Authorisation - Solid Organ and Tissue Donation (Scotland)

**MPD1043** - National Organ Retrieval (NORS) Mobilisation

**NOP001** - Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation

The Quality and Safety of Organs Intended for Transplantation - a documentary framework, 2012, Updated July 2014, Human Tissue Authority, [www.hta.gov.uk](http://www.hta.gov.uk)

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**1. INTRODUCTION**

- 1.1. In deceased and living donation and transplantation, a thorough assessment must be performed to enable characterisation of the donor and donated organ.
- 1.2. In deceased donation, the SNOD is responsible for collating all relevant donor information, and communicating with the RPoC and the NHSBT Duty Office. Any findings that could affect the integrity and safety of the organ for transplant must be communicated to the RPoC. The RPoC is responsible for communicating information to the implanting surgeon.
- 1.3. Before retrieval begins, the retrieving surgeon must verify that all required information is available, and also identify any further information that may be required. There may be occasions when the retrieving surgeon discusses any abnormal findings directly with the implanting surgeon.
- 1.4. In living donation, the LDC is responsible for collating all relevant donor information and communicating with the donor and recipient medical teams, including the retrieving and implanting surgeons. In UKLDSS, the LDC (donating centre) is responsible for communicating with NHSBT to register special considerations that may impact on the integrity and suitability of the donated organ prior to kidney donor matching runs. The LDC (donating centre) and the NHSBT Living Donor Scheme Co-ordinator communicate this information to the LDC/RPoC in the recipient centre. At time of surgery, the LDC/retrieving surgeon in the donating centre will liaise with the LDC/RPoC/implanting surgeon to discuss additional relevant information that could affect the integrity and safety of the donated organ.
- 1.5. Before proceeding to transplantation, the implanting surgeon must ensure that they have received all relevant information to permit donor and organ characterisation.

**2. VERIFICATION OF DONOR IDENTITY PRIOR TO RETRIEVAL**

**2.1. DECEASED DONATION**

- 2.1.1. Each retrieving surgeon is responsible for confirming donor identity prior to retrieval.
- 2.1.2. The deceased donor will have two name bands attached. As a minimum there will be three forms of identification: name, date of birth and hospital/CHI number.
- 2.1.3. Retrieving surgeons must ensure that donor identity details correlate with those recorded in the medical records, on the confirmation of death documentation, on the consent/authorisation documentation, and on any other documentation/investigation reports/results.
- 2.1.4. Verification that patient identity has been checked will be recorded on the Retrieval Checklist on DonorPath.

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**2.2. LIVING DONATION**

- 2.2.1. The retrieving surgeon is responsible for confirming donor identity prior to retrieval.
- 2.2.2. The living donor will have two name bands and identification will be made according to local Trust/Board policy. There will be three forms of identification: name, date of birth and hospital/CHI number.
- 2.2.3. Retrieving surgeons must ensure that donor identity details correlate with those recorded in the donor's medical records, on the relevant operation consent, and on any other documentation/investigation reports/results.
- 2.2.4. Verification that donor identity has been checked must be recorded on the pre-operative checklist.

**3. VERIFICATION OF CONSENT/AUTHORISATION FOR ORGAN/TISSUE DONATION PRIOR TO RETRIEVAL - DECEASED DONATION**

- 3.1. The SNOD will have obtained consent/authorisation for organ donation during donor assessment.
- 3.2. Consent/authorisation will be documented on **FRM4281** (England, Wales and Northern Ireland) or **FRM1538** (Scotland).
- 3.3. The retrieving surgeon must verify that consent/authorisation for organ/tissue donation has been given.
- 3.4. The retrieving surgeon must also establish which organs/tissues are to be donated and for what purpose/s consent/authorisation has been given.
- 3.5. Verification that consent/authorisation for organ donation has been checked must be recorded on the Retrieval Checklist on DonorPath.

**4. VERIFICATION OF CORONER PERMISSION, OR PROCURATOR FISCAL CONSENT, TO ORGAN DONATION - DECEASED DONATION**

- 4.1. Where required, the retrieving surgeon must check that the Coroner/Procurator Fiscal has been informed.
- 4.2. The retrieving surgeon must check that the Coroner has given permission to organ donation, or that the Procurator Fiscal has given consent.
- 4.3. Coronial permission will be documented on DonorPath and appears on EOS Core Donor Data Form (England, Northern Ireland and Wales).
- 4.4. Procurator Fiscal consent will be documented on Authorisation Form **FRM1538** (Scotland).
- 4.5. Verification of coroner consent, must be checked from the Core Donor Data Form.

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**5. VERIFICATION OF CONSENT FOR ORGAN DONATION PRIOR TO RETRIEVAL - LIVING DONATION**

- 5.1 Surgical consent for living organ donation is a two stage procedure according to surgical best practice (i.e. NHS Consent process). Written consent will be obtained by a suitably qualified member of the surgical team during living donor evaluation and documented in the donor's medical records.
- 5.2 Consent will also be obtained for NHSBT to hold information about the donor prior to donation.
- 5.3 Confirmation of donor preference regarding re-implantation, or reallocation of the donated organ (should it not be possible to implant it into the intended recipient), will be established and documented in the donor's medical records at the time of obtaining surgical consent, in accordance with Human Tissue Authority (HTA) requirements.
- 5.4 According to HTA requirements, the fully evaluated living donor will be Independently Assessed to ensure that consent can be given freely and voluntarily, and that there is no evidence of coercion or reward. Subject to these requirements, HTA approval to proceed with the donation is granted. .
- 5.5 On admission for donor surgery, the implanting surgeon will confirm consent (Part 2), and that HTA approval has been obtained and is current. This will be documented in the donor's medical records.

**6. VERIFICATION OF DONOR CHARACTERISATION PRIOR TO RETRIEVAL**

6.1. Information required for the characterisation of donors and donated organs will be collected by the SNOD in deceased donation, and by the LDC in living donation.

6.2. In **deceased donation**, the SNOD will

6.2.1. Undertake a thorough assessment of the potential donor to ensure an accurate medical, behavioural and travel history is available. Sources of information may include

- Medical records from the current admission
- Medical records from past admissions
- Information from the General Practitioner
- Information from other specialists e.g. oncologists
- Information from the potential donor's family including information regarding medical, behavioural, travel history

6.2.2. Collate the results of relevant diagnostic tests including

- Blood tests
- Blood group
- Virology
- Imaging/cardiology
- Screening for infections

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- 6.2.3. Undertake a physical examination of the potential donor, and facilitate any further examination or assessments required, to identify factors that could have an impact on the quality and safety of organs for transplantation and/or investigations indicated however not able to be undertaken.
- 6.3. Information will be recorded on DonorPath which will then populate the Core Donor Data form, and the Patient Assessment Form.
- 6.4. As specified in the NORS Standard document MPD1043, it is the retrieving surgeon's responsibility to check the information specified in Points 6.2 and 6.3 before proceeding to retrieval
- 6.5. As specified in the NORS Standard document MPD1043, the retrieving surgeon must also check that brain stem death, or circulatory death, has been confirmed and documented in the donor's medical records.
- 6.6. Verification that all relevant donor information has been checked must be recorded on the Retrieval Checklist on DonorPath.
- 6.7. In **living donation**, the LDC, in conjunction with Registered Medical Practitioners (RMPs) within the transplant medical team, will undertake a thorough assessment, of the potential donor, including a physical and psychological evaluation, to ensure an accurate medical, family and social history. This assessment must be consistent with principles of best practice as specified in national and local standards, guidelines and policies (e.g. the British Transplantation Society/Renal Association UK Guidelines for Living Donor Kidney Transplantation, SaBTO).
- 6.8. This assessment will be documented in the donor's medical records.
- 6.9. In **deceased and living donation**, the retrieving surgeon must review the information collated during the assessment of the potential donor, before retrieval, and ensure that factors that could affect the quality and safety of organs for transplantation have been identified and appropriately investigated.

## 7. PERIOPERATIVE ASSESSMENT OF DONOR AND ORGAN CHARACTERISATION

- 7.1. Principles of best practice, as specified in national and local standards, guidelines and policies, should be applied to the peri-operative assessment of donor and organ characterisation (e.g. the NORS standards, the British Transplantation Society/Renal Association UK Guidelines for Living Donor Kidney Transplantation, SaBTO).
- 7.2. The retrieving surgeon is responsible for:
- Peri-operative assessment of the donor and donated organ/s.
  - Taking all reasonable steps to assess for evidence of previously unidentified co-morbid disease in the donor (in particular malignancy) that could affect the quality and safety of the donated organ/s.

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- Identifying any disease process that could affect the suitability of an organ for transplant, and ensuring that it is discussed immediately with the implanting surgeon.
- Ensuring the NHSBT Duty Office is informed immediately if malignancy is identified in an organ from a deceased donor, so that the information can be relayed to all relevant recipient teams.
- Ensuring the RPoC and implanting surgeon are notified immediately if an organ appears sub-optimal, or if any damage or unexpected abnormality is encountered which might compromise the function or safe use of that organ.
- Signing the completed organ specific forms **FRM4194/4147/4121/4122**, recording which organs have been removed from the body, all abnormalities/anomalies, organ damage, sub-optimal perfusion or donor instability during retrieval.
- Documenting full details of the donor operation in the donor's medical record, including:
  - Which organs and tissues have been removed from the body
  - Any abnormalities/injuries noted

7.3. The retrieving surgeon must sign the medical records entry and print their name and the name of the retrieval centre with a contact telephone number.

## 8. RECEIPT OF THE DONOR ORGAN AT THE RECIPIENT CENTRE

8.1. The receipt of an organ at a recipient centre must be recorded. The responsible person receiving the organ must record the date and time of arrival, this must then be transcribed onto the HTA B form. It is recommended that if an organ label arrives with the organ that this is signed with a date and time. The responsible person receiving the organ must:

- Confirm the identity of the person delivering the organ. This should be done through proof of identification via a badge of the transport company, with photographic evidence of the transport personnel.
- Confirm the type of organ that is being delivered and its point of origin, and ensure that these details are consistent with those specified by the NHSBT Duty Office/RPoC/donating hospital LDC.
- Check that the security tag number on the organ box correlates with that given by the NHSBT Duty Office/RPoC/donating hospital LDC.
- Check that the organ transport box is structurally intact and fastened securely (where possible).

8.2. If using standard cold storage boxes the level of ice in the organ transport box must be checked, and more ice added, if required, to ensure that the organ is completely covered.

8.3. The organ must remain in the transport box/system in a secure location at the recipient centre until it is transferred into the operative field for implantation.

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8.4. For traceability, records of organs arriving at a recipient centre must be stored for 30 years (see *NOP006 v2 Transfer And Storage Of Donor And Organ Characterisation Information and Storage Of Traceability Data*).

**9. VERIFICATION OF DONOR AND ORGAN CHARACTERISATION AT THE RECIPIENT CENTRE**

9.1. Principles of best practice, as specified in national and local standards, guidelines and policies, should be applied to the verification of donor and organ characterisation at the recipient centre (e.g. NORS Standards, British Transplantation Society/Renal Association UK Guidelines for Living Donor Kidney Transplantation, SaBTO).

9.2. The implanting surgeon is responsible for:

- Checking the integrity of the organ, and the suitability of the organ for the recipient.
- Ensuring that they have received all relevant information about the donor and donated organ to enable a decision to be made on its suitability for implantation.
- Ensuring that identity details on all documentation and tissue samples (where relevant) accompanying the organ are checked and correlate with those given to the RPoC/LDC. As a minimum, this will include 3 unique identifiers:
  - In deceased donation: donor ODT number, date of birth and hospital number/CHI number.
  - In living donation: donor name, date of birth and hospital number/CHI number, ODT Recipient number.
- Checking that the organ has been transported appropriately to maintain quality and safety, and within an acceptable ischaemic time.
- Ensuring that the Organ Specific Form **FRM4194/4147/4121/4122** and, in deceased donation, the witnessed blood group form accompanying the organ in the transport box, are reviewed.

9.3. Recipient centres must immediately report to the Duty Office at NHSBT any abnormality found which contributes directly to donor and organ characterisation

**10. IMPLEMENTATION AND AUDIT**

1.1. The National Operating Procedures (NOPs) are available to download from the NHSBT ODT Clinical website at [www.odt.nhs.uk](http://www.odt.nhs.uk)

10.1. Transplant Units may

- Adopt the NOPs fully
- Adopt the NOPs with local adaptation
- Write their own procedural documents

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- 10.2. If the NOPs are not fully adopted, Transplant Units must ensure that local procedures are compliant with the requirements of the EU Directive and in accordance with the regulatory framework of the HTA: *The Quality and Safety of Human Organs Intended for Transplantation - a documentary framework*.
- 10.3. Accountability for the NOPs and their implementation will lie with each individual Transplant Unit.
- 10.4. Transplant Units will be responsible for
- Implementation of the NOPs according to local Trust/Board policy
  - Document review according to local Trust/Board policy, and in response to developments in organ donation and transplantation practice, or changes in national policy or guidance
  - Document control
  - Staff training

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