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Theatre Manual for Deceased Organ Donors

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Note: – This Manual is to be utilised by a qualified and trained SNOD. If the SNOD is in training, this Manual is to be utilised under supervision.

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Summary of changes/Introduction

Removed references to INOAR.

Review of the document to comply with the new procedural documents.

Inclusion of procedural documents.

Clarification around what needs to accompany organs for research and disposal of organs. Inclusion of flowchart to summarise roles and responsibilities in regards to packaging.

The changes listed above were changed in previous versions (v2/v3). Both versions were activated but never made effective due to the delays in the INOAR project. Therefore, to release the other changes in the SOP, the INOAR changes were removed under v3.1. Specialist Nurses were provided training to the above changes when training for version 2 and 3 was provided.

INTRODUCTION

POLICY

The organ retrieval/removal operation requires a co-ordinated approach to ensure the safe and timely retrieval of organs for transplantation and removal of organs for research from deceased organ donors. The SNOD is responsible for organising and co-ordinating organ retrieval/removal at the donor hospital, ensuring full completion of Donor Path.

The SNOD is also responsible for ensuring that communication is maintained throughout and that the patient is cared for in a dignified and respectful manner. In order to safeguard potential transplant recipients, to ensure traceability, and to minimise any potential risk, it is vital that organs for transplantation and their accompanying blood and tissue samples, and organs for other/scheduled purposes are collected, labelled and transported appropriately. It is a requirement under the HTA regulation 11 that the licence holders must ensure that a record of the transportation of organs arriving and/or leaving the establishment is kept as part of the traceability information including the consignment record documentation.

PURPOSE

This document aims to assist the SNOD in organising the organ retrieval/removal operation. It will outline the SNOD's role in facilitating the pre and peri-operative process of Donation following Circulatory Death (DCD), or Donation following Brain Stem Death (DBD), including the support for patient's families.

This document outlines the joint responsibilities of the SNOD and OPP regarding the entire retrieval/removal process. The document will outline the SNOD's responsibility in theatre in ensuring that the organ retrieval/removal process occurs in a co-ordinated and timely manner, with minimal disruption to the donor hospital, and the overriding principle of respect for the consented/authorised donor and safety of potential recipients is ensured.

The document is also to guide and inform those involved in the organ donation process on how to collect, label and facilitate the transportation of consented/authorised organs for transplantation (plus accompanying blood and tissue samples) and organs for other/scheduled purposes.

Note:

If the patient is being cared for outside the ICU when referred to the SNOD, best practice would indicate a negotiation with the medical practitioner to transfer the patient to the ICU whilst the organ donation process is facilitated. This is so that they and their family can be cared for in an environment more appropriate for withdrawal of life sustaining treatment and end of life care. It is the medical practitioner's ultimate decision to transfer a patient.

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Note:

A Donor Record must be completed for all consented/authorised organ donors as confirmation of actions below through the utilisation of Donor Path. In the event of unavailability follow the manual process as described in SOP3925 Manual Organ Donation process for a Potential Organ and/or Tissue Donor in the event of Donor Path/IT network unavailability which may include completion of FRM4212.

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Organising Solid Organ Retrieval

1. FOLLOWING CONSENT/AUTHORISATION FOR ORGAN DONATION

1.1. After consent/authorisation for retrieval of organs has been ascertained, the SNOD must inform the theatre coordinator in the donating hospital of the pending organ retrieval/removal and document it in the donor record.

2. INTRODUCTION TO THE THEATRE CO-ORDINATOR

- 2.1. The SNOD must introduce themselves to the theatre coordinator, exchanging contact details. In addition, information about handover times and the name and contact details of the person who will be co-ordinating the following shift must be gained to ensure continuation of effective communication.
- 2.2. The SNOD must take this opportunity to discuss the planned organ retrieval process and ascertain from the theatre staff if they have ever been involved in organ retrieval before. The SNOD must address any questions or concerns that they may have at this time. INF1424 can be utilised.

3. ORGANISING A THEATRE TIME

3.1. The SNOD must negotiate an agreed estimated theatre time taking into consideration the organs to be retrieved, theatre space and local staff availability. The SNOD must inform the theatre coordinator at the earliest opportunity of any changes or developments in the process that would affect the planned theatre retrieval.

4. DCD DONATION

- 4.1. The SNOD must confirm where Withdrawal of Life Sustaining Treatment (WLST) is taking place with the theatre coordinator and critical care unit staff, considering the hospital policy for DCD donation.
- 4.2. The SNOD must assess the area for planned WLST, ensuring that it is appropriate for continuation of end of life care and privacy for the family.
- 4.3. The SNOD must ensure that the relevant donating hospital staff are clear about the withdrawal process and have understood their roles and responsibilities in the process. Attention must be paid to the family's wishes at the point of death, timing of declaration of death and transfer to the operating theatre.
- 4.4. The SNOD must explain to the staff that the patient may not become asystolic within the time frame for donation in which case repatriation of the patient to critical care or to a ward bed may be necessary. This must be discussed and arrangements in place prior to withdrawal of treatment.

5. ORGAN OFFERING

- 5.1. Hub Operations will ensure that all potential donor organs are offered to transplant centres, subject to <u>POL188</u>.
- 5.2. Hub Operations will advise the SNOD of offering sequences for DCD heart.

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- 5.3. If a potential DCD donor is subsequently diagnosed dead by neurological criteria during preparations for retrieval and consent/authorisation for DBD donation is in place, organ retrieval may be delayed whilst the organs are re-offered by Hub Operations. This will only occur if the SNOD has gained agreement for subsequent delays from the patient's family. If recipients have already been identified and notified for transplant through the DCD process, these recipient centres may still allocate those organs for these recipients, as per MPD1043.
- 5.4. Hub Operations will not commence offering of cardio-thoracic organs until the HLA has been received.
- 5.5. If organs fulfil fast track criteria and fast track offering is commenced, organs must not be deemed un-transplantable until the end of the fast track period. Hub Operations should confirm with the SNOD at the end of the fast track period whether an organ has been accepted. This also applies when organs are accepted and then subsequently declined and fast tracked during the theatre process.
- 5.6. If transplantable organs cannot be placed in the UK, the SNOD must contact Hub Operations to discuss the possibility of placing the organs in Europe considering potential for delays in the process. The SNOD must document these discussions in the donor record.

6. ACTUAL THEATRE TIME: ACTIVATING THE NATIONAL ORGAN RETRIEVAL TEAMS

- 6.1. The SNOD must liaise with the theatre coordinator and confirm that a staffed theatre is still available prior to requesting NORS mobilisation.
- 6.2. When either an abdominal and/or a cardiothoracic organ has been accepted and ready for a NORS team to mobilise, Hub Operations will contact the SNOD. The SNOD will notify Hub Operation of their planned theatre time. Hub Operations will then initiate mobilisation of the NORS team following SOP4574.
- 6.3. A NORS team cannot be mobilised 5 hours ahead of a planned theatre time by Hub Operations. Hub Operations will ask the SNOD to ring back at the appropriate time point. It is the SNOD's responsibility to contact Hub Operations as they understand the activity within the Trust/Board they are working in. In exceptional circumstances an RM can be contacted for advice by the SNOD if they need to go outside of the 5-hour rule.
- 6.4. If a DBD, and a full abdominal and cardiothoracic donor, then Hub Operations will ask for the cardiothoracic team to arrive an hour ahead of the abdominal team as per INF1459. If a DCD and a full abdominal and cardiothoracic donor, then Hub Operations will ask for the NORS teams to arrive at the same time.
- 6.5. The NORS team will liaise with the SNOD confirming the organs and/or tissues to be retrieved for transplant, or removed for other/scheduled purposes. When appropriate, the SNOD must also communicate any organs accepted for specific research or for removal for other/scheduled purposes. The SNOD must communicate any specific requests from the accepting centres to Hub Operations when the NORS team/s are being activated via the nominated RCPOC. This will ensure that the team arrive with suitable resources for the planned retrieval/removal as guided by MPD1043.



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- 6.6. The SNOD must document all communication with the NORS retrieval team(s) and any other parties when arranging for the appropriate organ transport boxes and equipment to be brought to the donating centre. These entries must be documented in the 'Sequence of Events' section of the Donor Record.
- 6.7. The NORS team or their transport provider, will notify Hub Operations if they encounter delays and/or do not expect to arrive at the donor hospital at the agreed time. Hub Operations will share this information with the SNOD.
- 6.8. The SNOD must communicate with Hub Operations if any changes are expected to the theatre time. Hub Operations will share this information with the NORS team and, if applicable, the accepting researcher.
- 6.9. NORS mobilisation times and arrival times must be recorded in the donor record.

7. REQUIREMENTS FOR ORGAN RETRIEVAL/REMOVAL PROCESS

- 7.1. The SNOD must inform the local theatre team of the equipment required during the retrieval/removal process as per INF1424.
- 7.2. The SNOD must ensure that they contact the local hospital staff who will be present in theatre to discuss if they have ever assisted in an organ retrieval and detail what will be required of them.
- 7.3. Where lungs are to be retrieved, the SNOD must ascertain the location of the blood gas analyser and confirm that this can be accessed by local staff during the retrieval operation. In the case of DCD lung donation, the use of INF1425 can be utilised at this point for discussion with anaesthetists.

8. THEATRE PREPARATION

- 8.1. In conjunction with staff at the donor hospital the SNOD must ensure that arrangements have been made for transfer of the donor to the identified theatre.
- 8.2. For DBD patients the SNOD must commence the transfer the patient to theatre where possible, when the NORS teams are within 30 minutes of the hospital.
- 8.3. The SNOD must complete the pre-operative checklist in the donor record prior to handover to NORS lead surgeon.
- 8.4. The SNOD must ensure that a witnessed copy of the patient's blood group is available for each organ to be donated for transplantation and that sufficient blood samples have been procured prior to theatre for donation.
- 8.5. If organs are retrieved for transplantation, but then declined by recipient centres, and accepted for research, then the organs will be packed in the same way. Lymph, spleen and blood will accompany the organs, with the appropriate HTA-A Form.
- 8.6. The NORS lead surgeon must review the donor documentation and medical records as guided by the pre-operative checklist. The SNOD must document this handover of information in the 'Retrieval' section of the donor record.

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8.7. The NORS lead surgeon must perform a 'Surgical Pause' as part of this checklist to ensure that hospital and retrieval team members are aware of their purpose in theatre and clarify any final points prior to retrieval. Confirmation of this action is documented by the SNOD in the 'Retrieval' section of the donor record.

9. TRANSFER TO THEATRE

9.1. The SNOD must aim to minimise manual handling risks when assisting the local donating hospital staff transferring the patient from the critical care unit to the operating table. The NHSBT manual handling guidance can be accessed at http://nhsbtweb/userfiles/odt%20gen%20007%2014008.pdf
When visiting local hospitals, the team will be guided by the trust policies and staff to ensure adherence to local policy.



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Consent/Authorisation obtained for Organ Retrieval/Removal

- Inform Theatre Coordinator of planned retrieval/removal of organs
- Exchange contact details
- Estimated retrieval times
- <u>INF1424</u> may be given to theatre staff.

DCD

SNOD

DBD

- Complete the demographics of the HTA-A form.
- Collect all blood samples prior to theatre/WLSTlabel with 3 PID, date and time. Note the CT OPP will collect any additional bloods during DBD.
- Complete demographics and consent part of The Transplant Vessels and Tissue Form.
- Ensure that all stickers are filled out.

OPP Abdo Responsibility

- Perfusion and Perfusion documentation and timings on HTA-A form.
- Ensuring the tissue samples, vessels, are identified, retrieved, stored and labelled appropriately for organs for transplant.
- Appropriate packaging of an organ.
- Ensure completion of Transplant Vessels and Tissue Form (retrieval surgeon section onwards).

Surgeon responsibilities

- Ensure completion of and sign HTA-A and necessary vessels form.
- Complete medical entry in medical notes.

OPP CT Responsibility

- Perfusion and Perfusion documentation and timings on HTA-A forms.
- To collect any additional blood samples during DBD- centre specific- for example blood cultures.
- Ensuring tissue samples and vessels are identified, retrieved, stored and labelled appropriately for organs for transplant.
- Appropriate packaging of an organ, ready for immediate dispatch.
- Ensure organ is handed over to transport personnel.

SNOD/OPP Responsibility

- In conjunction will ensure that all relevant material accompanies. the organ, including paperwork, checking against 3 PID.
- Seal the box together.

SNOD Responsibility

- Packaging heart for valves.
- Final sign off for all abdominal organs, and handover to transport personnel.

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Organ Retrieval: Pre-Theatre

10. COMMUNICATION POST CONSENT/AUTHORISATION FOR ORGAN RETREIVAL/REMOVAL

- 10.1. The SNOD must communicate clearly with the ICU/theatre staff and inform them that consent/authorisation for organ retrieval has been obtained. This will allow the hospital staff time to prepare for WLST/transfer and organ retrieval/removal and also enable the SNOD to answer any questions the staff may have. INF1424 may be given and utilised by theatre staff.
- 10.2. The family must be kept informed at all times with explanations for any examinations and/or interventions undertaken. Please refer to POL162 and associated procedural documents for further guidance and advice.
- 10.3. The SNOD must document all relevant conversations held with HCP's in the donor record.

11. PREPARATION FOR WLST/ORGAN RETRIEVAL/REMOVAL

- 11.1. The SNOD must confirm and identify:
 - the location where WLST will take place
 - Mode of WLST
 - End of life care comfort measures/pathways instigated.
- 11.2. Wherever the location of WLST, the SNOD must consider the logistics of patient transfer. The SNOD must also clarify:
 - Location on critical care unit for WLST.
 - Location of anaesthetic room for WLST size to accommodate family members, if relevant.
 - Path for transfer to theatre
 location of theatres in relation to location/area of WLST.
 - Personnel required portering staff/HCP requirements for transfer of patient.
 - Communication pathway contact details of NORS team for critical information during WLST, to minimise any organ damage secondary to ischaemic times.
- 11.3. Prior to WLST the SNOD must confirm the following with the Lead Retrieval or Implanting surgeon(s):
 - Method of communication between SNOD and retrieval team.
 - Frequency of update on patient's clinical condition.
 - Stand down times.
 - Roles and responsibilities of theatre team/NORS retrieval team/SNOD/local anaesthetist/OPP's.
 - The SNOD must confirm the volume and type of blood samples required to accompany each transplant/tissue retrieval with the NORS retrieval team(s)/RCPOC's/Tissue Establishment. The SNOD must facilitate the collection of blood samples prior to WLST and ensure that they are labelled with the patient's name plus 3 points of identification:
 - ODT/Donor Number
 - Date of Birth
 - Hospital Number/CHI Number (Scotland)



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Additionally, the date and time that the sample was taken must be clearly written on the label of each tube.

Please note- the CT OPP will collect any additional bloods, for example blood cultures, during DBD retrieval.

- 11.4. The SNOD must identify the medical practitioner who will certify death following WLST. A discussion must be held between the SNOD, the appropriate medical practitioner and nurse, to include:
 - Availability of the medical practitioner following WLST and methods of communication to ensure they return to the location of WLST, when circulatory death is imminent if unable to remain present.
 - An explanation of the critical time points during the WLST process.
 - The importance of timely documentation of certification.
 - Pre-populated certification of death paperwork must not be utilised.
 - A discussion surrounding the possible re-intubation between the local anaesthetist and the NORS must be facilitated by the SNOD if the patient is for DCD lung retrieval, as per INF1425.
 - Instigation of end of life comfort measures to minimise any potential distress to the patient and patient's family, if present.
 - Repatriation of patient if donation does not proceed. This may be applicable if WLST occurs outside of the ICU.
- 11.5. The SNOD must confirm which HCP will remain with the patient and their family during the process of WLST. The SNOD must also ensure that a member of the local hospital staff is available to accompany the family to an appropriate location and provide support, whilst the SNOD is in theatre.
- 11.6. The SNOD must confirm the plan for WLST with the theatre co-ordinator so that all members of the donating hospital team are aware of the planned course of action.
- 11.7. The SNOD must facilitate a discussion with the patient's family to confirm with them the planned course of action, giving as much or as little information as requested by them. The patient's family must be prepared for potential physiological changes that can occur following WLST. This must be done in conjunction with the donating hospital staff. Areas to discuss may include but are not limited to:
 - Confirmation of mode of withdrawal of treatment.
 - End of life comfort measures.
 - Documentation of observations.
 - Asystole and five-minute period prior to confirmation of death (pronouncement of life extinct).
 - Confirmation of death prior to transfer.
 - Transfer to theatre for organ retrieval/removal.
 - Support for family post confirmation of death.
 - Family plans following confirmation of death.
- 11.8. The SNOD must confirm the family's understanding of the possible eventuality that donation may not proceed, as per the discussion during the consent/authorisation process.
- 11.9. Any questions and concerns raised by the family must be addressed and their immediate needs met, prior to proceeding further, and documented in the donor record.



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11.10. The SNOD must document, in the donor record, all relevant conversations held with HCP's and any agreements reached in relation to WLST and transfer plans.

12. ACTIONS TO BE TAKEN PRIOR TO AND FOLLOWING WLST

- 12.1. The SNOD must complete the pre-operative checklist in the Donor Record prior to handover to NORS lead surgeons(s). If Donor Path is unavailable FRM4135 must be completed prior to the organ retrieval/removal process commencing.
- 12.2. If Donor Path is unavailable <u>FRM4135</u> must be utilised for the pre and peri-operative checks as per SOP3925.
- 12.3. The SNOD must record the necessary key time points in the Donor Path DCD section and DCD observations during the withdrawal of treatment process. If Donor Path is unavailable utilise FRM4131 and FRM4153. This must also be documented in a visible place within the theatre.
- 12.4. Once death has been certified by the medical practitioner, the SNOD must follow the plan of action agreed with the patient's family (if applicable) and relevant HCP's.

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In Theatre Support, Collection, Labelling and Transport (Organs and Samples)

13. IN THEATRE

- 13.1. The SNOD must maintain a presence in theatre to ensure co-ordination of the retrieval/removal process.
- 13.2. The SNOD must take into consideration the requests of the Recipient Centres, and communicate these with the NORS Team. Such requests may include photographs of the organs, weight or extra vessels. The actions taken need to be documented within Donorpath (MPD1100)
- 13.3. The SNOD must support the theatre staff and aid communication between the theatre staff and visiting teams.
- 13.4. Perfusion will be undertaken by the OPP as per MPD889.
- 13.5. As part of the organ retrieval process, blood and tissue samples (i.e. lymph and spleen) must accompany a transplant to allow the recipient centres to undertake any necessary tissue typing and additional microbiological testing. In addition, blood vessels may also be required to aid the implanting surgeon during the transplant operation.
- 13.6. There is a vital role in ensuring that the required blood vessels and tissue samples are identified, retrieved, stored and labelled appropriately by the OPP, with the pre-populated stickers which are completed by the SNOD.
- 13.7. The OPP must facilitate the appropriate packaging of an organ for transplant, with the required blood, blood vessels, tissue samples and relevant paperwork, to ensure that any risk to the organ recipient is minimised.
- 13.8. It is the responsibility of the SNOD to complete the demographic sections within the HTA-A forms.
- 13.9. It is the responsibility of the OPP to complete the perfusion fluid batch numbers, and timings on the HTA-A forms.

14. COMMUNICATION DURING THE RETRIEVAL/REMOVAL PROCESS:

- 14.1. The SNOD must liaise with the respective RCPOC's/Hub Operations/Tissue Establishments to identify what information they require during the procedure and communicate it accordingly e.g. information about the progression of the retrieval.
- 14.2. The SNOD must ensure that all relevant information regarding the retrieval has been entered into the Donor Record. In the event of limited/no connectivity, updated information should be communicated to Hub Operations by the SNOD.

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15. PRE-THEATRE COLLECTION OF BLOOD SAMPLES

- 15.1. The SNOD must obtain relevant blood samples pre theatre for DCD and DBD retrieval, and ensure that sufficient blood samples are available to accompany all of the organs for transplant. The SNOD must ensure that relevant blood samples are also taken, if the family have consented/authorised to tissue donation.
- 15.2. It is the responsibility of the cardiac OPP to obtain relevant blood samples for transplant, when facilitating a DBD retrieval. The SNOD must document all relevant communication with the recipient centres in the 'Sequence of Events' section of the Donor Record.
- 15.3. The SNOD must ensure that the sample(s) include the patient's name plus 3 points of identification:
 - ODT/Donor Number
 - Date of Birth
 - Hospital Number/CHI Number (Scotland)

Additionally, the date and time that the sample was taken must be clearly written on the label of each tube by the SNOD.

15.4. Once all of the blood samples have been appropriately labelled, the SNOD must handover the blood samples to the OPP, who must then place the blood samples in a sealable sample pouch and store in the relevant organ box in preparation for organ handover.

Note:

The SNOD and OPP must ensure that they utilise Universal Precautions when handling blood, blood vessels, organs and tissue samples. Refer to POL173 Infection Prevention and Control in NHSBT for details of Universal Precautions

16. RECORD OF TIMINGS DURING RETRIEVAL/REMOVAL PROCESS

- 16.1. The SNOD must record all the necessary key time points during the retrieval/removal process, as required for the Donor Record.
- 16.2. Agreed timings must be reported to the RCPOC as arranged at the time of acceptance of an organ.
- 16.3. All timings must be recorded in a visible area within the theatre. A photograph must be taken and added to the Donor Path file, ensuring that the picture is taken in accordance with MPD1100.

17. FINDINGS REQUIRING ADDITIONAL ACTION DURING THE RETRIEVAL/REMOVAL PROCESS:

- 17.1. Any findings requiring additional action must be reported by the SNOD to Hub Operations/RCPoC's/accepting transplant surgeon as quickly as possible, as per MPD881.
- 17.2. The Lead Surgeon must document any abnormalities/anomalies, organ damage, suboptimal perfusion or donor instability during the procedure on the HTA-A Organ Specific and/or HTA-A Research form and in the patient's medical records.

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17.3. In the event pregnancy is detected during the organ retrieval process please refer to MPD891.

18. COLLECTION AND LABELLING OF TISSUE SAMPLES AND BLOOD VESSELS IN THEATRE

- 18.1. It is the OPP's responsibility to obtain the organ specific tissue samples i.e. lymph nodes and spleen, and blood vessels to accompany organs for transplant. Ensuring that each container seals appropriately and has no faults (for example cracks, faulty lid).
- 18.2. Blood vessels must accompany the liver and pancreas/pancreas for islets for transplantation.
- 18.3. In the event of cardiothoracic only organs, these tissue samples are still required to accompany the organ. The agreed responsibility must be recorded in the 'Organ Packaging' section of the Donor Record.
- 18.4. At the appropriate time during the organ retrieval process, the OPP must confirm with the retrieval surgeon and scrub practitioner directly the quantity of tissue samples required. The OPP must ensure that there are sufficient samples of lymph nodes and spleen to accompany each organ for transplant to the recipient centres. Refer to MPD1043.
- 18.5. It is the OPP's responsibility to attach the label, which the SNOD has pre-populated to each sample/vessel container, with the specific tissue or vessel contained. This must include the patient's name plus 3 points of identification:
 - ODT/Donor Number
 - Date of Birth
 - Hospital Number/CHI Number (Scotland)
- 18.6. The OPP will present the tissue sample containers which will be filled with preservation fluid prior to the tissue samples (lymph and spleen) being placed in the containers by the NORS scrub practitioner.
- 18.7. The blood vessel container(s) must remain sterile at all times. The OPP must ensure that the blood vessels are secured inside a sterile container before accepting them from the scrub practitioner.
- 18.8. When directed by the scrub practitioner/retrieval surgeon, the OPP must facilitate the receipt of the tissue samples/blood vessels into the containers, confirming verbally the specific tissue/vessels received.
- 18.9. The OPP should then place the tissue sample/blood vessels containers into the sealable sample pouch, containing the blood sample taken earlier, and store this in the relevant organ box in preparation for organ handover.
- **18.10.** If an organ is subsequently declined for transplant, and is now for other/scheduled purposes, the lymph, spleen and vessels will still accompany the organ. The HTA-A Form must accompany the Organ.



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- 18.11. If the SNOD/OPP is informed by the lead abdominal retrieval surgeon that it is not possible to fulfil requirements, for example extra vessels, then the SNOD must contact the RCPOC as a matter of urgency to ensure that the implanting surgeon is aware and a decision can be made on whether to continue to accept the organ for transplant. The SNOD must document any relevant communication with RCPOC in the donor record.
- 18.12. The Transplant Vessels and Tissue form must be completed with the following responsibilities:
 - 1. SNOD completes demographics section
 - 2. SNOD to sign regarding appropriate consent/authorisation
 - 3. OPP completes rest of the form
 - 4. Surgeon signs the form

The OPP must place the blood vessels inside the specimen bag.

18.13. The completed Transplant Vessels and Tissue form with the relevant vessels must be sealed within a sample pouch and placed within the organ box with the relevant organ, in readiness for organ handover, by the OPP.

Note:

If the accepting centre wish to attend the retrieval to enable use of novel technologies, they will be responsible for ensuring all of the above OPP responsibilities are completed (including gaining and labelling of samples and paperwork).

PACKAGING OF AN ORGAN FOR HANDOVER

Note:

Organ Packing Guide for SNODs and OPPs must be used to guide the OPP/SNOD when packaging kidneys,

pancreas/pancreas islets, liver and heart for valves.

- 18.14. When cardiothoracic organs and/or multi-visceral organs/novel organs/tissue are being retrieved/removed, the responsibility for safely packaging the organ, blood and tissue samples lies with the NORS cardiothoracic and/or multi-visceral/specialist surgical team.
- 18.15. When an organ is ready to be packed in the organ box the OPP must undertake the following actions:
 - The OPP must confirm that the organ has been prepared for packing as per MPD1043.
 - The OPP must verbally state the organ they are receiving from the scrub practitioner and where appropriate whether this is the left or right organ. The prepared organ must also have a colour coded tie on the outer packaging, where appropriate, which verifies the identity of the organ.
 - The OPP must ensure that the organ is placed in the box without delay, and adequately covered by melting water ice.
 - The OPP must place an extra cable tie in a sample pouch at this stage to facilitate re-sealing the box where this is necessary. This pouch should be placed above the ice inside the box.
 - The OPP must ensure that the boxes are prepared for placement of the organ/tissue as soon as is reasonably practicable after commencement of the

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retrieval/removal operation. Coloured organ identification labels must be attached to the boxes prior to the OPP accepting the organ from the NORS team.

19. COMMUNICATING KIDNEY ANATOMY

19.1. The SNOD must communicate the kidney anatomy as obtained from the lead retrieving surgeon, clearly and accurately, to Hub Operations to help identify the most suitably matched recipient.

20. DOCUMENTATION TO ACCOMPANY AN ORGAN

- **20.1.** The SNOD must ensure that the patient details, demographic sections are completed on all of the HTA-A Organ Specific Forms.
- 20.2. The OPP must complete the perfusion fluid section and the timings on the HTA-A Form, including batch numbers.
- 20.3. The SNOD can, if they feel able to do so, in collaboration with the surgeon, write the kidney anatomy and populate the fields on the HTA-A Form.
- 20.4. All the forms must include a legible name and contact telephone number of the appropriate lead retrieval surgeon. The top copy of the organ specific forms should be retained for the donor file. The donor file must be returned to DRD within 5 days.
- 20.5. It is the retrieval surgeon's responsibility to ensure completion of and to sign HTA-A, and necessary vessel forms.
- 20.6. It is the SNOD's responsibility to ensure that the following documentation is sealed within the organ box. The documents must be sealed in a waterproof bag and placed in the box alongside the organ and associated samples
 - HTA-A Organ Specific Form accompanies transplant organs.
 - Photocopy of witnessed blood group form accompanies all organs retrieved for transplantation.
- 20.7. The SNOD must document the box numbers on the organ handover sheet (FRM4217). A record of these box numbers must be kept by the SNOD and recorded in the 'Organ Packaging' section of the Donor Record. Where an organ is being transported using machine perfusion, such as the LifePort or Transmedics systems, the number recorded must be from the unique machine ID or 'asset' number.

21. SEALING THE ORGAN BOX

- 21.1. The SNOD and OPP must close the organ box but not seal it until all samples and documentation have been placed inside and are ready for handover.
- 21.2. The SNOD, in collaboration with the OPP must ensure that all blood, tissue samples and vessels required are in situ and the accompanying paperwork has been completed before sealing the organ box for abdominal organs. The SNOD must also ensure that the labelling of all samples is correct. The SNOD will take final responsibility for ensuring the correct packaging of the organ and associated samples as required in readiness for handover. The SNOD must complete the 'Organ Packaging' section of the Donor Record.

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- 21.3. The SNOD and OPP must seal the organ box utilising the appropriate security tag/cable tie. The box number for the organ must be relayed to the Hub operations/NRC/SNBTS to assist with identification and organising transport from the donating hospital to the recipient centre.
- 21.4. For CT organ retrieval/removal, the CT OPP will take final responsibility for ensuring the correct packaging of the organ and associated samples (as required), in readiness for handover. There may be occasions where the CT OPP, is not able to step away from the retrieval for handover. On these occasions the CT OPP must liaise with the SNOD to ascertain if they are able to handover the organ to the transport personnel.
- 21.5. Heart for tissue donation to be packaged by the SNOD.
- 21.6. Documentation to accompany heart for tissue donation should be in accordance with NRC/SNBTS requirements.

22. ARRANGING TRANSPORT OF AN ORGAN

- 22.1. The table below outlines responsibilities for those involved in the organ retrieval/removal process; (some recipient centres arrange their own kidney/pancreas transport. Hub Operations will advise if this is the case).
- 22.2. In all cases where an organ is not being transported by the NORS retrieval teams, the SNOD must identify from the RCPOC/Hub Operations which transport company will be arriving to collect the organ for transport and if they have arranged the transport for the organ. Information regarding the transport company will be provided to the SNOD by the RCPOC/Hub Operations prior to the organ being released for transport.

Mode of Transport	Responsibility to arrange transport
Accompanied – Organ accepted by recipient centre that supplied NORS retrieval team.	NORS retrieval team have responsibility to accompany the organ back to the recipient centre with them.
Unaccompanied - Heart, Lungs, Liver, multi-visceral organs	RCPOC has responsibility to arrange additional transport.
Unaccompanied – Kidney or Pancreas	Hub Operations has responsibility to arrange transport.
Unaccompanied – Heart donated for heart tissue donation	NRC/SNBTS contact has responsibility to arrange transport.

- 22.3. If heart for tissue is being donated, the SNOD must ensure the National Referral Centre (NRC) / Scottish National Blood Transfusion (SNBTS) contact arranges transport for collection of the heart at the end of the retrieval operation (SOP5024).
- 22.4. The SNOD must confirm an estimated time for organ handover with the retrieval surgeons during the organ retrieval/removal process. The SNOD must communicate with the relevant RCPOCs, NRC/SNBTS staff and Hub Operations to ensure that transport arrangements are made in a timely manner. The SNOD must document any relevant communication with RCPOCs for the donor record.

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22.5. Update Hub Operations if the NORS Team are unable to stay to retrieve organs for other/scheduled purposes.

23. HANDOVER OF AN ORGAN TO TRANSPORT PERSONNEL

- 23.1. The SNOD must confirm the identity of the transport personnel for each organ being transported utilising photo ID.
- 23.2. The SNOD must also confirm with the transport personnel their understanding of which organ they are collecting, the box number and its correct destination.
- 23.3. The SNOD will have completed the corresponding organ box label (or sticker <u>FRM4318</u>) with the full address.
- 23.4. Transport personnel (including NORS staff or implanting theatre staff at donating centre) must enter their details onto the relevant section of the organ box label (or sticker FRM4318) thereby documenting custody of the organ box from the SNOD.
- 23.5. The SNOD must complete the relevant sections of <u>FRM4217</u> for each organ/tissue box handed over and document their actions in the 'Sequence of Events' section of the Donor Record.

NOTE:

The purpose of the <u>FRM4217</u> and the organ box label or sticker (<u>FRM4318</u>) is for traceability of organs and supporting material such as tissue and blood samples where these are contained in a separate organ box.

24. DELAYS IN PLACING ORGANS FOR TRANSPLANT/RESEARCH 24.1. ORGANS FOR TRANSPLANT

- 24.1.1. Where the NORS team are ready to leave theatre and an organ is still to be handed over for onward transport for transplant, the SNOD must speak directly with Hub Operations to establish the potential for further delay. If the delay is longer than the anticipated SNOD presence in theatre, then the SNOD must speak with the OPP and request that the organ accompany them back to their transplant centre.
- 24.1.2. The OPP is responsible for taking the organ back to a designated location at the NORS base (e.g. a particular ward or theatre that is staffed 24/7).
- 24.1.3. The OPP must confirm the location where the organ will be stored at the NORS transplant centre, and identify a member of staff (e.g. RCPOC/NORS contact). The OPP will inform the SNOD of location and contact details.
- 24.1.4. The SNOD will then provide Hub Operations with a name and direct-line contact number for that location and individual with whom Hub Operations can communicate with to arrange subsequent transport arrangements for the organ. Hub Operations will offer the organ out to approved research studies, if there is appropriate consent/authorisation for research. If there is no response after 45 minutes, then the organ will be disposed of as per hospital policy, ensuring HTA-B form is completed.

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24.2. ORGANS REMOVED FOR OTHER/SCHEDULED PURPOSES

- 24.2.1. An organ must never be left unaccompanied in the donating hospital for collection by transport personnel unless the donating hospital is a transplant centre, and a healthcare professional acting in the role of RCPOC, is willing to accept receipt of the organ and be available for contact by Hub Operations. If this is not the case, escalation to the TM/RM on call may be required.
- 24.2.2. If an organ is declined for transplant and research, and is to be disposed of after the NORS team has left, but the donor is in a non-transplanting centre, then the SNOD must organise with Hub Operations for the organ to be sent to a transplant centre for disposal. Completion of the HTA-B form to be completed by the person accepting the organ at the transplant centre. There must be a conversation between SNOD and the accepting centre, and an agreement with the plan. This must be clearly documented within donorpath/the donor file.
- 24.2.3. The SNOD must contact Hub Operations to advise them of the time that the NORS team depart.

25. COMPLETION OF THE ORGAN RETRIEVAL/REMOVAL PROCESS

25.1. The Lead surgeon from each team is responsible for producing an accurate account of the retrieval/removal process in the patient's medical records including all organs/tissues removed and any anomalies found. This should also take account of any Coronial or Fiscal requests for information to be detailed. All entries to be signed and dated and a contact telephone number added as per MPD1043.

26. CARE AFTER DEATH:

- 26.1. The SNOD must attempt to facilitate any specific requests made by the family following the organ retrieval/removal process.
- 26.2. The family may have accepted the offer to participate in care after death and/or sharing in religious or cultural rituals as per MPD845. The SNOD must support this decision and facilitate as local policy/practice allows.
- 26.3. The family may wish to spend time with the patient following the organ retrieval/removal process. The SNOD must always undertake the act of final care as per national guidance and local policy.
- 26.4. The SNOD must document the condition of the patient's body following care after death procedures in the patient's medical records for example, body cleaned, no oozing or excessive oozing present, incision site dressed appropriately and copied for the donor file.
- 26.5. If the patient is to donate tissues /eye tissue following organ retrieval/removal, then a referral to NRC/SNBTS should be made following the process described in SOP5024.
- 26.6. The SNOD must liaise with local theatre/portering staff to facilitate the safe transfer of the patient to the mortuary.
- 26.7. In Scotland as per LET242, a name-band must be placed on the patient's wrist giving instructions to the pathologist, in the event of a post mortem being carried out.

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27. LEAVING THEATRE

27.1. The SNOD must liaise with the donating hospital theatre staff to ensure that the operating theatre is left in an acceptable condition as per local hospital policy, post retrieval/removal process. The SNOD must ensure that following the organ retrieval/removal process that all external equipment and paperwork has been removed.

27.2. The SNOD must provide contact details to the theatre co-ordinator.

28. NON-PROCEEDING DONATION

- 28.1. If all recipient centres/tissue/research establishments decline the offer of organs and/or tissues for donation, then the SNOD must inform the relevant HCPs/Hub operations/ Laboratories that donation will not proceed.
- 28.2. If donation cannot proceed for example, due to patient instability, family circumstances or protracted time to asystole, the SNOD must inform Hub Operations of stand down time.
- 28.3. The SNOD must inform the family of reason for non-proceeding donation if no RCPOC's accept organs or if standing down from donation after WLST. If the patient's family is not present, the SNOD must follow the agreed communication pathway discussed during the consent/authorisation process to outline to the patient's family why organ and/or tissue donation could not proceed.
- 28.4. If the SNOD requires support in the case of non-proceeding donation, they should contact the TM/RM/ on call RM for advice and guidance.
- 28.5. If advised by the TM/RM on call RM, the SNOD must report the reason for donation not proceeding via NHSBT on-line Clinical Governance system at the earliest opportunity post process so that the management team can analyse the sequence of events, and reasons for non-donation. The SNOD must ensure their TM is aware that an incident report has been submitted as per SOP3888.
- 28.6. The SNOD must change the status on the Donor Record to non-proceeding explaining the reason why donation could not proceed.
- 28.7. The SNOD must also document clearly the sequence of events in the donor record, and via the EOS Referral/PDA forms, giving clear details as to the reasons why donation could not proceed.
- 28.8. In the cases of a non-proceeding DCD, the SNOD must dispose of any blood samples as per local hospital policy and in line with SOP5024.

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Organ Packing Guide for OPP's and SNOD's

The purpose of this INF is to guide and inform those involved in the organ retrieval/removal process on how to collect, label and facilitate the transportation of organs and their accompanying documentation, blood and tissue samples.

Prior to leaving NORS base, the OPP must check the integrity of the organ boxes. On arrival of NORS team in theatre, the OPP must ensure there are sufficient transport boxes for the organs to be donated, or removed for other/scheduled purposes. The OPP must ensure the boxes are structurally intact and there is sufficient melting water ice for packing. There should also be sufficient pouches to safely transport samples and documentation inside the sealed box with the organ. Please ensure that the valve is always closed when ice is in the box, please see image below. The OPP must ensure organ boxes are brought for organs to be removed for other/scheduled purposes. The organ box is able to be clearly labelled to show which organ is being transported, and an approved NHSBT organ transport label/sticker is available



1. Do not open the window section on the lid. This is sealed closed on purpose and you may cause permanent damage to the box by forcing this open.





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2. The OPP will prepare the box lid by securing **one side** of the lid (if not already secured) with the supplied cable ties in the manner shown. Insert the cable tie through the plastic hook with lid open, pass the cable tie through the grey side panel before locking the lid with the side panel. Secure the lid using the cable tie.







Close latch hole in latch and secure the tie (place finger behind tie to ensure you do not over-tighten)- see pictures below.



3. The box should be prepared by the OPP in readiness for the organ being accepted from the NORS personnel. You do not need to line the box with clear bags. The volume of melting water ice in the box should be sufficient to ensure the packaged organ will not be in contact with the box structure. Further melting water ice will be added later once the packaged organ is in place. A coloured label must be attached to the handle of the box prior to the organ being accepted by the OPP for packaging.





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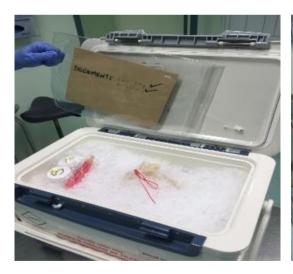
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4. The prepared box will have a sample pouch for safely storing the lymph nodes, spleen and blood samples required to travel with the organ. These tissue samples will be placed in the box when handed to the OPP. A second sample pouch may be used for blood vessels or extra bloods requested by the recipient centre. The coloured tie around the outside of the packaged organ further denotes the organ within the box – the NORS personnel must additionally verbally confirm with the OPP the organ they are handing over. The coloured label and tie should match and assist in identifying the organ stored inside the box.

BLUE for PANCREAS/PANCREAS FOR ISLETS WHITE for HEART FOR TISSUE DONATION YELLOW for LEFT KIDNEY RED for RIGHT KIDNEY

En-bloc kidneys must have a **Red** and a **Yellow** label attached to the organ box. Where labels are not used, a generic organ sticker supplied in the donor pack must be applied to the organ box FRM4318.

5. The Organ Specific form and blood group should be placed within the organ box, within a separate waterproof plastic pouch, which is supplied by the OPP. An extra cable tie should be placed on top of the ice to allow the box to be re-sealed if opened prior to the final destination. It is the joint responsibility of the SNOD and OPP to ensure that all documentation and samples are labelled and completed correctly before sealing the organ box. The box lid should be sealed closed with a cable tie and the addresses applied to the labels once known, by the SNOD. Ensure both sides of the box are closed and secured. The ultimate responsibility that all items and documentation is present and correct, is that of the SNOD.





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6. Transport personnel taking custody of the organ will be informed of the box number by their organisation; this number can be found on the side panel of the box and must be documented by the SNOD. The last five digits on the box bar code number (after "AAA") must be recorded on the organ handover form by the SNOD and within the Donor Record. Whoever takes custody of an organ from the donating theatre must complete the label accordingly.







HANDLING THE PACKED ORGAN BOX

Boxes contain melting water ice and there is a risk that spilt water could cause slips, trips and falls. Please be aware of any spillages and ensure these are dealt with rapidly.

The boxes may weigh around 12.5 kg or less when packed with an organ, so precautions must be taken when lifting the boxes, particularly in restricted spaces, and when carrying the boxes. Avoid the need for any manual handling which might involve a risk of injury, so far as is reasonably practicable.

Where the need for manual handling is unavoidable, please ensure all staff are up to date in their manual handling training and use a wheeled trolley to carry the packed organ box.

OPENING THE PACKED ORGAN BOX

The coloured organ label should remain on the organ box until transplantation. It should then be kept with the recipient's medical records or until the date and time of receipt has been successfully and accurately transcribed on to the HTA B form. The coloured label can then be disposed of.

To open the box, cut the cable tie on **one side only** of the silver closing mechanisms with scissors:

Cut the cable tie here:





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Useful Information

1. Associated Documents

POLs:

POL162 - Donor Characterisation

POL173 - Infection Prevention and Control in NHSBT

POL188 – Clinical contraindications to approaching families for possible organ donation

MPDs:

MPD845 - Family Care

MPD873 - Physical assessment

MPD881 – Findings Requiring Additional Action

MPD889 - Abdominal Perfusion and Preservatio

MPD891 - Pregnancy in Donation

MPD1043 - National Standards for Organ Retrieval from Deceased Donors

MPD1382 - Donation Pathway Communication Touchpoints - SNODs and Hub Operations

SOPs:

SOP5024 – Tissue Referral Process

SOP3888 - Reporting an Organ Donation or Transplantation Incident to NHSBT

SOP4574 - Logistics and NORS Mobilisation Manual- Hub Operations

SOP3925 - Manual Organ Donation Process for a Potential Organ and/or Tissue Donor in the event of DonorPath/IT network unavailability

SOP4442- Allocation of Organs and Tissue for Research and Novel Technologies- Hub Operations

INFs:

INF1424 – Basic Guidelines for Theatre Staff at Donor Hospital

INF1425 - Care of Potential Lung DCD Donors - Safety Brief

INF1459 - NORS mobilisation Single Process

FRMs:

FRM4131 - DCD Observation Chart

FRM4135 - NHSBT Surgical Safety Checklist

FRM4153 - Proceeding and Non-Proceeding Donors after Cardiac Death

FRM4212 - Organ Donation Pathway

FRM4318 - Organ Box Address Sticker

FRM4217 - Organ Handover Form

FRM6199 - Transplant Vessels and Tissues

2. Incident Reporting

An incident may occur within the chain of organ donation and transplantation for which there is a legal requirement to report under the Regulations. Additionally, an incident may occur for which we may benefit from organisational or national learning.

These incidents should be reported to the ODT Directorate of NHSBT using the following link https://safe.nhsbt.nhs.uk/IncidentSubmission

3. Other Useful Links

NHSBT/BTS Guidelines for Consent for Solid Organ Transplantation in Adults (2013) http://www.odt.nhs.uk/pdf/guidelines_consent_for_solid_organ_transplantation_adults.pdf

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SaBTO Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation (2011)

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_121497

SaBTO Position statement on West Nile Virus

https://www.gov.uk/government/publications/west-nile-virus-and-solid-organ-transplantation-sabto-statement

SaBTO Guidance on the Transplantation of Organs from Deceased Donors with cancer or a history of cancer 2014

https://www.gov.uk/government/publications/transplantation-of-organs-from-donors-with-a-history-of-cancer

Council of Europe: Criteria for preventing the transmission of neoplastic diseases in organ donation. Council of Europe Publishing (2006)

http://128.121.10.98/coe/pdfopener?smd=1&md=1&did=514115

Council of Europe: Guide to the quality and safety of organs for transplantation https://www.edqm.eu/en/organ-tissues-cells-transplantation-guides-1607.html

Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). http://www.hta.gov.uk/licensingandinspections/licensingunderthequalityandsafetyregulations.cfm

Confidentiality: NHS Code of Practice 2003

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253

Confidentiality: NHS Code of Practice: Supplementary Guidance: Public Interest Disclosures (Nov 2010)

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh 122031.pdf

JPAC

http://www.transfusionguidelines.org/

4. NHSBT Guidance on Information Governance

http://nhsbtweb/resources/information_governance/nhsbt_guidance/index.asp

5. Secure Email

Secure email is between <u>NHSBT</u> accounts or between <u>NHSBT</u> to <u>nhs.net</u> and between <u>nhs.net</u> accounts.

http://nhsbtweb/resources/information_governance/information_security/index.asp



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Definitions

DCD – Donation following Circulatory Death.

DBD - Donation following Brain Death.

DonorPath – Secure electronic system that SNODs utilise to register potential organ donors and upload donor characteristics prior to organ offering using an iPad or PC. DonorPath also creates and stores an electronic donor record of the donation process.

DoH – Department of Health.

DRD – Donor Records Department.

CLOD – Clinical Lead Organ Donation.

CHI Number - Community Health Index number (unique patient identifier used in NHS Scotland).

DRD – Donor Records Department.

ED – Emergency Department.

EOS – Electronic Offering System.

EOS Mobile – Electronic Offering System used by Transplant Centres to review the Donor Characterisation information.

ODR - Organ Donor Register.

ODST – Organ Donation Services Team.

ODT – Organ Donation and Transplantation, a directorate within NHSBT.

OPP – Organ Preservation Practitioner.

Genius Scan - Genius Scan IPAD Application associated with NHSBT authorised IPADS.

HCP – Health Care Professional.

HTA – Human Tissue Authority.

HUB Operations – To receive information communicated by the SNOD in relation to box/tag numbers for kidneys. To arrange transport for kidneys and pancreas.

ICU - Intensive Care Unit.

Medical Practitioner – facilitates the WLST process.

NHSBT - NHS Blood and Transplant.

NORS – National Organ Retrieval Service.

NTLC - National Transplant Liaison Co-ordinator.

Lead Retrieval Surgeon - Refers to the Lead Surgeon for Abdominal and/or Cardiothoracic retrieval.

Patient Family - for the purposes of this document "patient family" refers to the family, friends and significant others of the patient.

PID - Patient Identifiable Data.

RCPOC – Recipient centre point of contact –a nominated nurse or surgeon who is contacted to discuss and consider an organ offer for their transplanting centre.

RM – Regional Manager.

Scrub Practitioner(s) – receives information from RCPOC regarding the patient and specific items required for the retrieval.

SNOD – (Specialist Nurse Organ Donation) - for the purposes of this document the terminology 'SNOD" will apply to Specialist Nurse with the relevant knowledge, skills and training in organ donation, working within NHSBT Organ Donation Services Teams (ODST).

TM – Team Manager.

Transport Personnel - take receipt of and transport the organ to the recipient centre, ensuring the required documentation is complete.

Theatre Coordinator – Nurse in charge of the donating hospital theatre department. Facilitates theatre provision and local staff to assist the NORS team.

WLST – Withdrawal of Life Sustaining Treatment.