

Theatre Manual for Deceased Organ Donors

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

Summary of changes

Addition to 11.2 regarding the new visibility of timings in the 'Retrieval Information' tab that does not replace verbal updates to Hub and Receiving Centres (Page14)

Addition to 17.9 regarding use of Significant findings or new clinical information identified during retrieval that require further explanation must be documented in the specific 'Organ Retrieval / New significant clinical information' box (Page 18)

Amended practice in 'Organ Packing Guide for OPP's and SN's' section relating to discontinuation of cable ties for closure or organ boxes, and using tamper proof organ box sealing tape from April 2025 (pages 21, 24 and 31 to 35)

Introduction

POLICY

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

The SN 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 SN in organising the organ retrieval/removal operation. It will outline the SN'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 SN and OPP regarding the entire retrieval/removal process. The document will outline the SN'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.

Advice

If the patient is being cared for outside the ICU when referred to the SN, 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.

Advice

A Donor Record must be completed for all consented/authorised organ donors as confirmation of actions below through the utilisation of DonorPath. All clinically significant information must be communicated on the CDDF ( Wifi symbol area of DonorPath) and focus on contemporaneous documentation to ensure interface with Transplant 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 DonorPath/IT network unavailability which may include completion of **FRM4212**.

Organising Solid Organ Retrieval/Removal

1. FOLLOWING CONSENT/AUTHORISATION FOR ORGAN DONATION

- 1.1. After consent/authorisation for retrieval/removal of organs has been ascertained, the SN must inform the theatre coordinator in the donating hospital of the pending organ retrieval/removal and document it in the donor record.
- 1.2. In the circumstance of an implantable device (pacemaker, defibrillator, temporary pacing wire) being identified on physical assessment or medical notes review, it is essential to consider management during end-of-life care and any actions required. Management of these devices must be led by the treating clinical team, involving cardiology as required.

2. INTRODUCTION TO THE THEATRE CO-ORDINATOR

- 2.1. The SN 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 SN must take this opportunity to discuss the planned organ retrieval/removal process and ascertain from the theatre staff if they have ever been involved in organ retrieval/removal before. The SN 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 SN must negotiate an agreed estimated theatre time taking into consideration the organs to be retrieved/removed, theatre space and local staff availability, and any specific study requirements (if applicable). In DBD cases it may be appropriate at introductions to advise the theatre coordinator of the possibility of a required expedited process should a liver be accepted for transplant within the Super Urgent pathway. Rationale for urgency and timings should be provided. The SN must inform the theatre coordinator at the earliest opportunity of any changes or developments in the process (such as above) that would affect the planned theatre retrieval/removal.

4. DCD DONATION

- 4.1. The SN 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 SN 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 SN 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 SN 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.

- 4.5. For donors with death confirmed using Neurological Criteria (DBD) progressing on a DCD pathway. The National Organ Donation Committee's position is that it is important to respect a donor family request to be with their loved one at the end of their life when cardiac activity ceases. In such circumstances it is unacceptable for the heart to restart, even if the confirmation of death remains valid. Five minutes is the safe standard for the prevention of autoresuscitation, as supported by the recent NEJM 2021 paper, and this should be the standard in the UK in all DCD pathways.

5. ORGAN OFFERING

- 5.1. Hub Operations will ensure that all potential donor organs are offered to transplant centres, subject to **POL188**. The Hub will also offer organs which have been consented/authorised for removal for other/scheduled purposes which are contraindicated for transplant (**POL188**), and those that were offered and declined by all centres for transplantation. Whole heart removal for valves and tissues will take priority over heart removal for research (**SOP4442**).
- 5.2. Hub Operations will advise the SN of offering sequences for DCD heart.
- 5.3. If a potential DCD donor is subsequently diagnosed dead by neurological criteria during preparations for retrieval/removal and consent/authorisation for DBD donation is in place, organ retrieval/removal may be delayed whilst the organs are re-offered by Hub Operations. This will only occur if the SN 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 SN 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 SN must refer to **MPD1682** and contact Hub Operations to discuss the possibility of placing the organs in Europe/Republic of Ireland. Any potential delays required in the process should be considered and balanced against family and hospital needs. The SN must document these discussions in the donor record. If organs cannot be placed for transplant in the UK +/- Europe/Republic of Ireland, then Hub Operations will commence offering of organs for other/scheduled purposes if there is appropriate consent/authorisation.

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

- 6.1. The SN must liaise with the theatre coordinator and confirm that a staffed theatre is still available prior to requesting NORS mobilisation.
- 6.2. Dependent on organs being offered, when either an abdominal and/or a cardiothoracic organ has been accepted for transplant the NORS team can be mobilised. Hub Operations will contact the SN to advise. The SN must advise Hub Operations of their

planned theatre time once confirmed. Hub Operations will mobilise the NORS team as per **SOP4574**.

- 6.3. In circumstances where the pancreas / split liver requires additional vessels the SN must facilitate a conversation between the Lead abdominal retrieval surgeon and the Transplanting surgeon to determine which vessels will travel with which organ. Only in exceptional circumstances, such as for re-transplantation and the creation of an arterial conduit, should additional vessels be requested at the time of retrieval (Carotid arteries or superior mesenteric artery). In this situation, consultant (liver) to consultant (pancreas) discussion must take place to determine which vessels will travel with which organs.
- 6.4. If aNRP is to be used, **SOP5917** must be referred to.
- 6.5. The NORS Team will not be mobilised purely for removal of organs for other/scheduled purposes.
- 6.6. In a QUOD Hospital (England, Wales and Northern Ireland), where there is appropriate consent/authorisation for removal of organs for other/scheduled purposes, Hub Operations will update the NORS team that the necessary kit must be brought. This applies to any Hospital in Scotland where a licence is not required to remove relevant material.
- 6.7. A NORS team cannot be mobilised more than 5 hours ahead of a planned theatre time by Hub Operations. Hub Operations will ask the SN to ring back at the appropriate time point. In exceptional circumstances an RM can be contacted for advice by the SN if they need to go outside of the 5-hour rule.
- 6.8. 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. 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. For a DCD heart theatre process please refer to **SOP4746**, in regard to arrival times for the NORS teams.
- 6.9. The NORS team will liaise with the SN confirming the organs and/or tissues to be retrieved for transplant or removed for other/scheduled purposes. When appropriate, the SN must also communicate any organs accepted for specific research or for removal for other/scheduled purposes as per **SOP5567** and **SOP5663**. The SN 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**.
- 6.10. If an approved research team will be attending theatre to remove organ/tissue, this must be communicated to the NORS team. Any queries/clarification that is required should be discussed directly between the NORS and research teams, at SN/NORS handover. Please refer to **SOP6496** for information relating to the SENTINEL Trial, and any other supporting study SOP for guidance.
- 6.11. The SN 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.

- 6.12. 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 SN.
- 6.13. The SN 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.
- 6.14. If there are coronial or procurator fiscal restrictions in place which could impact the retrieval, the SN must request that Hub Operations ask for the NORS team to contact them to discuss details.
- 6.15. NORS mobilisation times and arrival times must be recorded in the donor record.

7. REQUIREMENTS FOR ORGAN RETRIEVAL/REMOVAL PROCESS

- 7.1. The SN must inform the local theatre team of the equipment required during the retrieval/removal process as per **INF1424**.
- 7.2. The SN 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/removal and detail what will be required of them.
- 7.3. Where lungs are to be retrieved/removed, the SN must ascertain the location of the blood gas analyser and confirm that this can be accessed by local staff during the retrieval/removal operation. In the case of DCD lung donation, the use of **INF1425** can be utilised at this point for discussion with anaesthetists.
- 7.4. DCD Lung Removal for Research Please note: If there is a competent member of the local hospital or cardiothoracic retrieval team to intubate post diagnosis of death as per INF1425, DCD lungs may be removed ventilated and perfused for research. If intubation cannot be performed, DCD Lungs will be removed uninflated and un-perfused by the cardiothoracic team. These lungs can be successfully used for research and researchers will be willing to accept them. Removal of lungs for research will only happen if the lungs have been accepted by an approved research study.

8. THEATRE PREPARATION AND PRINCIPLES FOR COMPLETION OF THE ORGAN RETRIEVAL SAFETY CHECKLIST

- 8.1. In conjunction with staff at the donor hospital the SN must ensure that arrangements have been made for transfer of the donor to the identified theatre.
- 8.2. The SN must ensure that a witnessed hard 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. 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 (40ml EDTA will accompany a DCD/DBD heart instead of lymph and spleen for donors over 16yrs), with the appropriate HTA-A Form. If organs are being removed purely for other/scheduled purposes, or specific research, they will not be packed or perfused the same as organs for transplant. Lymph, spleen and blood will not accompany the organs. The HTA-A Research form will accompany the organ.
- 8.3. The Organ Retrieval Safety Checklist is based on the World Health Organisation Surgical Safety Checklist which is embedded across healthcare in the pre surgical setting. The Organ Retrieval Safety Checklist is not a SN to NORS handover form, rather a checklist to ensure patient safety.
- 8.4. The Organ Retrieval Safety Checklist is a core set of safety checks, identified for improving performance at safety critical time points within the donor's perioperative journey. It is not intended as a tick-box exercise but as a tool to initiate effective communication between the clinical NORS teams, the hospital team, and the SN.
- 8.5. Team briefing is an opportunity for highly effective face-to-face communication which can enhance team performance; however, it must be focused and supportive. Briefing facilitates delivery of clear messages and reduces misunderstandings; it is not just about informing people but listening and responding to questions and concerns. The completion of the checklist also serves as a 'surgical pause' or 'time out' that is advocated across healthcare and provides a designated time for team members to voice any concerns about the patient's safety or the procedure (which supports the culture of psychological safety).
- 8.6. The retrieval checklist available on DonorPath should not be completed. Instead, the SN and NORS Lead(s) should utilise **FRM7307** Organ Retrieval Safety Checklist and complete all sections on paper hard copy. Hard copy completion requires the lead surgeon(s) to print and sign their name, which emphasises their responsibility for the check and provides assurance of NORS team accountability.
- 8.7. The SN and Lead Surgeon(s) must complete Section 1A of **FRM7307** before the patient is moved to the Anaesthetic room (DCD) / Theatre (DBD).
- 8.8. Before the patient is moved to the Anaesthetic room (DCD) / Theatre (DBD) the NORS Lead(s) must complete section 1B of FRM7307 in conjunction with the SN, surgical team, anaesthetist (DBD), Organ Preservation Practitioners and local theatre team.
- 8.9. Sometimes it is necessary for DBD patients to be transferred to theatre when the NORS teams are within 30 minutes of the hospital. In this circumstance care must still be taken when completing section 1A and 1B remaining aware of the importance of the surgical pause.

- 8.10. Prior to surgical start for DBD donors the NORS Lead(s) must complete part 2.
- 8.11. In the case of DCD donors Part 3A of **FRM7307** must be completed before withdrawal of life sustaining treatment. Part 3B must be completed prior to surgical start. N.B. section 3B is permitted to be completed by the NORS perfusion practitioner on behalf of the lead surgeon.
- 8.12. If a research team is attending, they should be present for the Organ Retrieval Safety Checklist to discuss the intended process. Organs to be retrieved for transplantation take priority over research. There must be no delays to the donation process for research. Refer to the supporting study SOP for guidance.
- 8.13. Once completed, **FRM7307** should be uploaded to DonorPath as a document image.

9. TRANSFER TO THEATRE

- 9.1. The SN 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.

DCD and DBD Theatre/ Retrieval Responsibilities

RESPONSIBILITY / ACTION KEY

SN - Organ Donation

NORS

Consent/Authorisation obtained for Organ Retrieval/Removal

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

- Complete the demographics of the HTA-A form and HTA-A research form.
- Collect all blood samples prior to theatre/WLST- label with 3 PID, date and time. Note the CT OPP will collect any additional bloods during DBD.
- Complete section A of Transplant Vessels & Tissues Form (**FRM6199**)
- Ensure that all stickers are filled out.

OPP Abdo Responsibility

- Perfusion and Perfusion documentation and timings on HTA-A form and HTA-A Research form.
- Ensuring the tissue samples, vessels, are identified, retrieved, stored and labelled appropriately for organs for transplant.
- Appropriate packaging of an organ.
- Complete section B of Transplant Vessels & Tissues Form (**FRM6199**)

Surgeon responsibilities

- Ensure completion of and sign HTA-A and HTA-A Research forms and complete section B of Transplant Vessels & Tissues Form (**FRM6199**)

OPP CT Responsibility

- Perfusion and Perfusion documentation and timings on HTA-A forms and HTA-A Research 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.

SN/OPP Joint Responsibility

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

SN Responsibility

- Packaging heart for valves.
- Transcribe kidney anatomy in full onto DonorPath
- Final sign off for all abdominal organs, and handover to transport personnel.

Additional DCD Organ Retrieval/Removal: Pre-Theatre Guidance

N.B. to be read in addition to 1-9 above.

10. PREPARATION FOR WLST/ORGAN RETRIEVAL/REMOVAL

10.1. The SN must confirm and identify:

- the location where WLST will take place
- Mode of WLST
- End of life care comfort measures/pathways instigated.

10.2. Wherever the location of WLST, the SN must consider the logistics of patient transfer.

The SN 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.

10.3. Prior to WLST the SN must confirm the following with the Lead Retrieval or Implanting surgeon(s):

- Method of communication between SN and retrieval team. If using DonorPath and TransplantPath to communicate withdrawal observations, both parties to check connectivity prior to WLST. Key touchpoints, including asystole must continue verbally.
- Frequency of update on patient's clinical condition.
- Stand down times.
- Roles and responsibilities of theatre team/NORS retrieval team/SN/local anaesthetist/OPP's/research team (if applicable)
- The SN 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 SN 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
 - NHS Number/CHI Number (Scotland)Additionally, the date, time and location 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.

- 10.4. As per **FRM7307** Organ Retrieval Safety Checklist the SN must identify the medical practitioner who will verify death following WLST. A discussion must be held between the SN, 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 verification.
 - Pre-populated verification 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 SN if the patient is for DCD lung retrieval/removal, 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.
- 10.5. The SN must confirm which HCP will remain with the patient and their family during the process of WLST. The SN 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 SN is in theatre.
- 10.6. The SN 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.
- 10.7. The SN 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 verification of death (pronouncement of life extinct).
 - Verification of death prior to transfer.
 - Transfer to theatre for organ retrieval/removal.
 - Support for family post verification of death.
 - Family plans following verification of death.
- 10.8. The SN must confirm the family's understanding of the possible eventuality that donation may not proceed, as per the discussion during the consent/authorisation process. 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.
- 10.9. The SN must document, in the donor record, all relevant conversations held with HCP's and any agreements reached in relation to WLST and transfer plans.

11. ACTIONS TO BE TAKEN PRIOR TO AND FOLLOWING WLST

- 11.1. As per section 8 above, the SN must complete **FRM7307** sections 1A, 1B, 3A and 3B with the NORS Lead(s) prior to the organ retrieval/removal process commencing.
- 11.2. The SN must record the necessary key time points in the DonorPath DCD section and DCD observations during the withdrawal of treatment process. **Key timings relating to DCD theatre must be inputted on DonorPath in the 'Retrieval Information' tab labelled with a Wi-Fi symbol in real time (as soon as able). This makes the timings available to receiving centres via TransplantPath. This does not however replace verbal communication of these timings as per MPD1382 and any agreed centre requests. If DonorPath is unavailable utilise FRM4131 and FRM4153. This must also be documented in a visible place within the theatre.**
- 11.3. Once death has been certified by the medical practitioner, the SN must follow the plan of action agreed with the patient's family (if applicable) and relevant HCP's.
- 11.4. In some DCD donors, death has not occurred at 3 hours post WLST. There may be occasions where the NORS Lead surgeon may feel that the kidneys are still likely to be transplantable and wish to wait longer. This situation is often associated with a decline from the initial recipient centre, which prompts re-offering. In this situation, the process should continue, including organ retrieval, until offering has been exhausted, or until the kidneys are retrieved and sent to the accepting centre, or the NORS team wish to stand down. In this circumstance, if offering is still in progress when the NORS team, having retrieved the organs, are departing, they should take the organs with them whereupon transport can be arranged by recipient centres from the NORS base.

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

13. IN THEATRE

- 13.1. The SN must maintain a presence in theatre to ensure co-ordination of the retrieval/removal process.
- 13.2. The SN 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. All organ media (images and videos) should be taken via the DonorPath app. The actions taken need to be documented within Donorpath (**MPD1100**)
- 13.3. Best practice is for the SN to endeavour to complete DonorPath retrieval section in real time to allow visible sections to be viewed by recipient teams in TransplantPath.
- 13.4. The SN must support the theatre staff and aid communication between the theatre staff and visiting teams.
- 13.5. Please refer to NORS standards (**MPD1043**) regards surrounding tissue.
- 13.6. Perfusion will be undertaken by the OPP as per **MPD889**.
- 13.7. As part of the organ retrieval/removal 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. 40ml EDTA will accompany a DCD/DBD heart instead of lymph and spleen for donors over 16yrs. In addition, blood vessels may also be required to aid the implanting surgeon during the transplant operation. In circumstances for example H.M. Coroner or Procurator Fiscal restrictions where this is not possible discussions must be escalated and clear communication to recipient centres in advance is essential to ensure necessary Tissue Typing testing.
- 13.8. A DBD heart, not on a perfusion device, must be boxed and ready for dispatch within 30 minutes after cross clamp. Clear plans and observation of this time frame should be communicated in NORS handover and surgical planning between SN and NORS.
- 13.9. Organs removed for other/scheduled purposes do not require lymph, spleen and blood to accompany the organ. The organs will be packed as for a transplant organ with the HTA-A Research form accompanying.
- 13.10. 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 SN.
- 13.11. 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.

13.12. It is the responsibility of the SN to complete the demographic sections within the HTA-A and HTA-A Research forms.

13.13. It is the responsibility of the OPP to complete the perfusion fluid batch numbers, and timings on the HTA-A and HTA-A Research forms.

14. COMMUNICATION DURING THE RETRIEVAL/REMOVAL PROCESS:

14.1. The SN 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/removal.

14.2. The SN must ensure that all relevant information regarding the retrieval/removal has been entered into the Donor Record. In the event of limited/no connectivity, updated information should be communicated to Hub Operations by the SN.

14.3. For any INOAR organs declined by all transplanting centres and that are not suitable for tissues, inform Hub Operations and follow **SOP5567** and **SOP5663** for further information for research/other/scheduled purposes organs.

14.4. Hub Operations are to be advised if NORS team are able or unable to stay to remove research organs or the donor is non-proceeding. Researchers are to be updated by Hub Operations of this. The researchers will also be informed if the CT team have stood down, which will mean that the heart will now be removed by the abdominal team but will be un-perfused.

14.5. As part of organising the retrieval, clarification and agreement must be sought regarding the following with recipient co-ordinators, and must be clearly documented on DonorPath:

1. Mode of communication, including number/email address.
2. Times of communication which are required for the retrieval.
3. If using DonorPath / TransplantPath, ensure key touchpoints are agreed as TransplantPath will not alert RCPoCs.
4. Who will be responsible for the communication?

Please refer to **MPD1382** for communication points with Hub Operations.

15. PRE- THEATRE COLLECTION OF BLOOD SAMPLES

15.1. The SN 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 SN must ensure that relevant blood samples are also taken, if the family have consented/authorised to tissue donation.

15.2. Where a maternal microbiology sample is required, a further sample should be taken immediately prior to theatre transfer in circumstances where tissue donation is being facilitated, in line with JPAC guidance. This sample should be appropriately labelled and should accompany the tissue donation.

15.3. It is the responsibility of the cardiac OPP to obtain relevant blood samples for transplant, when facilitating a DBD retrieval. The SN must document all relevant communication with the recipient centres in the 'Sequence of Events' section of the Donor Record

15.4. Direct cross match request: If requested by the accepting centre, **only 40mls of blood in EDTA bottles** is required by all tissue typing laboratories.

15.4.1. By exception, bespoke requests for other cross-match blood can be considered, where clinically appropriate for the donor.

15.5. Organ specific bloods – Organ advisory groups have agreed a reduction in the volume of blood and type of samples that are required with each organ – see table below:

Organ	Blood bottle type number required		Additional information	Centre variance / comments
	EDTA	Clotted		
Lungs	0	1	Blood cultures may be requested	Glasgow and GOSH require NO clotted samples. Harefield require 2 clotted samples.
Heart	<u>Donors over 16yrs ONLY</u> 40ml EDTA (Replacing Lymph & Spleen)	1		Glasgow and GOSH require NO clotted samples. Harefield require 2 clotted samples.
Liver	0	0		Centres may request extra blood in case of positive virology where the local lab is unable to process on the clotted samples with vessels
Hepatocytes	0	2		
Vessels	0	2 – for each set of vessels	Minimum volume 14mls	If the liver is being split – please ensure you send 2 separate sets of bloods (ie. 4 clotted samples) to allow the vessels to be split with the liver. This applies if the liver is being split and some segments are sent for hepatocytes.
Kidney	0	1		
Pancreas / Islets	2	2		
Small bowel	0	1		

No additional bloods are required for research, including INOAR

ADVICE

Particular consideration should be made when sampling from **paediatric** patients, especially those under 30 kgs. Cumulative sampling of as little as 5% of the total blood volume can result in cardiovascular instability, please see **SOP5874** (Paediatric Manual) for further information.

Paediatric blood sampling bottles should be used and minimum volumes determined with transplanting centres. Where instability is considered a risk, consider sampling just prior to WLST or cross clamp.

15.6. The SN must ensure that the sample(s) include the patient's name plus 3 points of identification:

- ODT/Donor Number
- Date of Birth
- NHS number/CHI Number (Scotland)
- (On the rare occasion that the donor does not have an NHS number, then please use the hospital number)

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

- 15.7. Once all of the blood samples have been appropriately labelled, the SN 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.
- 15.8. **FRM6723** (Sample Form) is available for the SN to accompany blood samples as needed.

⚠ Advice:

The SN 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 SN must record all the necessary key time points during the retrieval/removal process, as required for the Donor Record and for each of the organ specific HTA-A and HTA-A Research forms.
- 16.2. Agreed timings must be reported to the RCPOC as arranged at the time of acceptance of an organ.
- 16.3. Prior to Cross Clamp, please ensure that the drivers for the heart (for transplantation), lungs, liver and small bowel are on site, and contact numbers available. Contact must also be made to Hub Operations to arrange the transport for kidneys and pancreas. And if appropriate, arrange transport for Heart for Valves as per **SOP5024**.
- 16.4. All timings must be recorded in a visible area within the theatre. A scan image using NHSBT approved scanning application must be taken and added to the DonorPath file, ensuring that the scanned image is uploaded in accordance with **MPD1100**. Attach to DonorPath file as miscellaneous labelled as 'Theatre Timings'

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

- 17.1. Any findings requiring additional action must be reported by the SN to Hub Operations/RCPoC's/accepting transplant surgeon as quickly as possible, as per **MPD881** and **SOP4938**. The SN must also update the action tracker system used in their region at the time of donation to inform ODST team on post donation follow up.
- 17.2. The Lead Surgeon must document any abnormalities/anomalies, organ damage, sub-optimal 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.
- 17.3. In the event pregnancy is detected during the organ retrieval/removal process please refer to **MPD891**.
- 17.4. If there is a finding which requires histopathology assessment; **SOP5352** should be followed and **FRM5867** be completed. **N.B.** For kidney biopsies, please refer to Appendix A, which outlines the priority order.
- 17.5. All findings requiring additional action, must be documented in a section of DonorPath that is visible to transplant centres (Wifi symbol area of DonorPath). **Significant findings or new clinical information identified during retrieval that require further explanation must be documented in the specific 'Organ Retrieval / New significant clinical information' box, within the 'Retrieval Information' section of DonorPath – detailed process is within SOP4938.**

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). 40ml EDTA will accompany a DCD/DBD heart instead of lymph and spleen for donors over 16yrs.
- 18.2. Lymph and spleen samples may not always be required to accompany organs, if there are Any Coronial restrictions on lymph and spleen samples must be escalated as needed (refer to **MPD865**). Donation and ultimately transplantation may still be able to proceed. Clear communication of samples that will be available to HI Laboratories and transplant centres is essential.
- 18.3. Blood vessels must accompany the liver and pancreas/pancreas for islets for transplantation. Two clotted blood samples must accompany each set of vessels, in addition to those accompanying the organ (liver and/or pancreas)
- 18.4. 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.
- 18.5. At the appropriate time during the organ retrieval/removal 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**.
- 18.6. It is the OPP's responsibility to attach the label, which the SN 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
 - NHS number/CHI Number (Scotland)
 - (On the rare occasion that the donor does not have an NHS number, then please use the hospital number)
- 18.7. 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.
- 18.8. 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.
- 18.9. 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.
- 18.10. 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.

- 18.11. If an organ is subsequently declined for transplant, and is now for other/scheduled purposes, the blood, lymph, spleen samples and vessels will still accompany the organ. The HTA-A Form must accompany the Organ. An organ needs to have been accepted by a research study prior to theatre for HTA-A Research form to be accompanying the organ.
- 18.12. If the SN/OPP is informed by the lead abdominal retrieval surgeon that it is not possible to fulfil requirements, for example extra vessels, then the SN 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 SN must document any relevant communication with RCPOC in the DonorPath record as a sequence of events entry. The SN must ensure any deviation from normal vessel requirement is documented in a section visible to accepting centres (Wifi symbol area of DonorPath).

If the liver is split in situ at the donor hospital, the **recipient consultant surgeons who will receive the two liver grafts must discuss in advance** which graft will be retrieved with the native arteries in continuity, and which graft will be allocated the donor iliac artery and vein

Only in exceptional circumstances, such as for re-transplantation and the creation of an arterial conduit, should additional vessels be requested at the time of retrieval (Carotid arteries or superior mesenteric artery). In this situation, consultant (liver) to consultant (pancreas) discussion must take place to determine which vessels will travel with which organs.

- 18.13. The Vessels form (**FRM6199**) must be completed in full with the following responsibilities:
1. OPP/Retrieval Surgeon responsibility - complete section B
 2. SN responsibility - complete section A
 3. The receiving centre responsibility – complete section C
 4. It is the SN's responsibility to take a scan image, using NHSBT approved scanning application, of the vessel Form (**FRM6199**) and attach to DonorPath, ensuring that the scanned image is taken in accordance with **MPD1100**. Attach to DonorPath file as miscellaneous, labelled as 'Vessel Form'
 5. The OPP must place the blood vessels inside the specimen bag.
- 18.14. Refer to **SOP5685** for packing requirements of Ad-Hoc vessels.
- 18.15. The completed Vessels form (**FRM6199**) 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.

PACKAGING OF AN ORGAN FOR HANDOVER

i Advice:

If the accepting centre wish to attend the retrieval/removal 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).

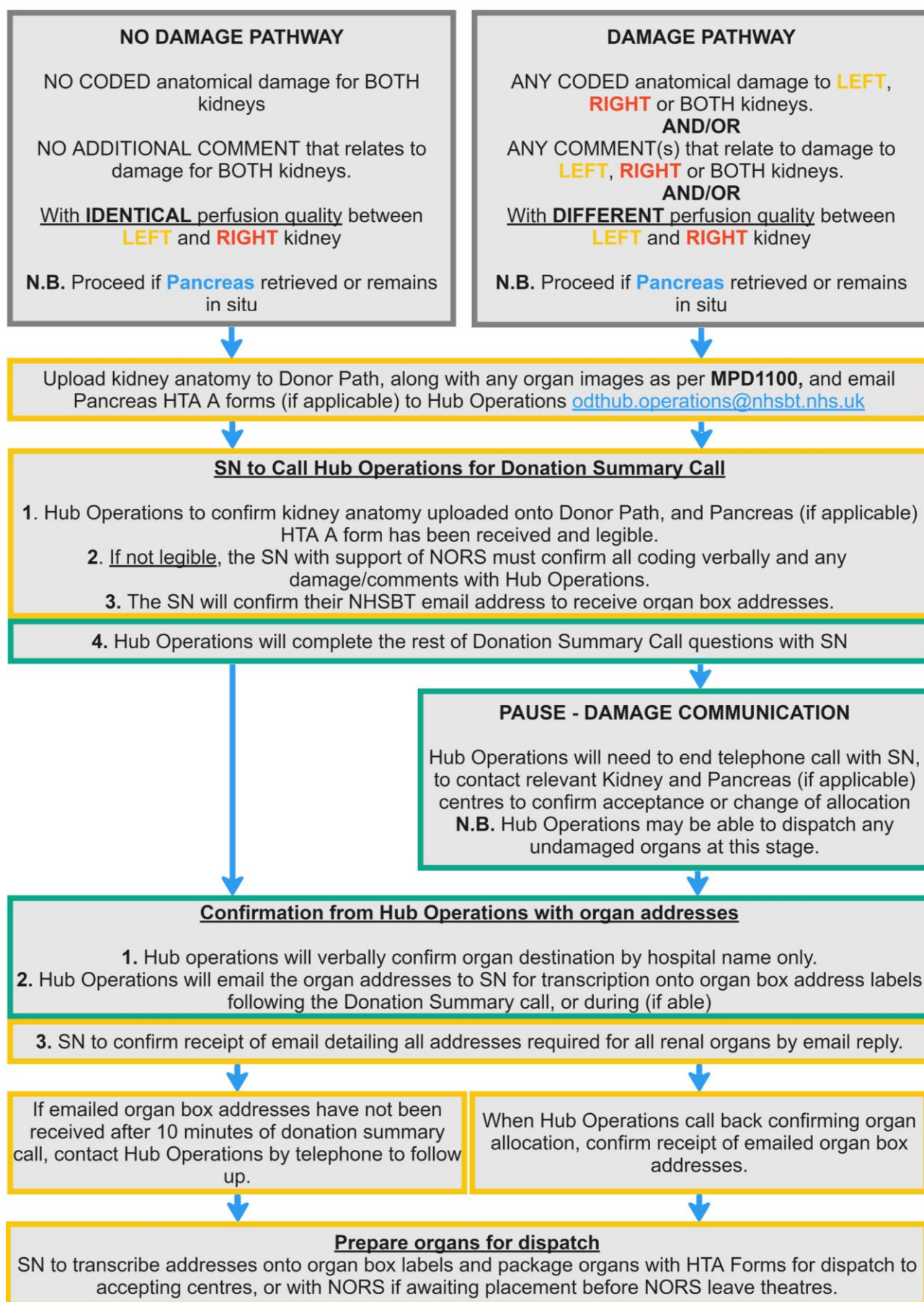
[Organ Packing Guide for SNs and OPPs](#) must be used to guide the OPP/SN when packaging kidneys, pancreas/pancreas islets, liver and heart for valves.

- 18.16. 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.
- 18.17. 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 or colour coded organ specific adhesive label on the second bag and on the outer bag/package, 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 **45cm length of organ box sealing tape** 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 retrieval/removal operation. Organ specific colour coded identification labels must be placed with the boxes ready for the address to be added prior to the OPP accepting the organ from the NORS team.

19. DONATION SUMMARY CALL

- 19.1. The SN will transcribe all kidney anatomy / comments / damage from the Kidney HTA-A form (**FRM4121** Kidney Donor Information) onto DonorPath in the 'Kidney Anatomy' section. The SN must clearly document which kidney the damage comments relate to. The Pancreas HTA-A form (**FRM4122** Deceased Donor Pancreas Information) must also be sent by email if accompanying as SPK or single solid organ for transplant/islets. Images of organs may be uploaded as per **MPD1100** at this stage also.
- 19.2. Standard anatomy of a kidney has been defined by the Kidney Advisory Group as: one artery on one patch, one vein, one ureter and no branches tied with no damage. Any deviation from this definition, is non-standard anatomy. A centre may make a request upon offer of a kidney, via Hub Operations, certain anatomical preference for their recipient's needs. Hub Operations will make the SN aware of this on organ acceptance.
- 19.3. The SN must facilitate the donation summary call following completion of the Kidney Anatomy section of DonorPath and sending of PDF Pancreas HTA A forms by email. As per **MPD1382**, answer all prompted questions. If Hub Operations confirm some details are illegible, on the emailed Pancreas HTA-A Form (**FRM4122**) this must be verbally clarified by the SN to Hub Operations to add the data to the donor notes and forward on to the relevant centres.
- 19.4. If this is not possible to upload kidney anatomy or share HTA A PDF forms by email, due to signal issues or IT failure, the SN must verbally 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. All uploads should be retrospectively completed on DonorPath when available.
- 19.5. The SN must clearly state if there is damage to any Kidney or Pancreas, or if either Kidney has different perfusion quality by stating either '**NO DAMAGE**' or '**DAMAGE**' pathway (See below).

- 19.6. If one organ is not damaged, this can still be dispatched ahead of centre update. Please inform Hub Operations which organ(s) is not damaged, and this will be considered on the call.



- 19.7. If SN is unable to send PDF and emails due to signal issues or IT failure, the 'No Damage' and 'Damage' pathways can still be used, but all Kidney Anatomy information will need to be verbally relayed to Hub Operations for transcription, who will forward on to accepting centres verbally.
- 19.8. Please ensure that you communicate with ODT Hub Operations following completion of the donation process (proceeding/non proceeding) to ensure a final handover is given and all details are closed off with the Hub. This is to ensure ODT HUB Operations have accurate records of organs retrieved for transplant, research, or other/scheduled purposes in line with regulatory compliance and donor family communication.

20. DOCUMENTATION TO ACCOMPANY AN ORGAN

- 20.1. The SN must ensure that the patient details, demographic sections are completed on all of the HTA-A Organ Specific Forms including the HTA-A Research form if organ removed for other/scheduled purposes.
- 20.2. The OPP must complete the perfusion fluid section and the timings on the HTA-A Form and HTA-A Research form, including batch numbers.
- 20.3. The SN 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 and HTA-A Research 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, HTA-A Research and necessary vessel forms.
- 20.6. It is the SN'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 and/or HTA-A Research form accompanies other/scheduled purposes organs.
 - Photocopy of witnessed blood group form accompanies all organs retrieved for transplantation.
 - If kidneys are retrieved, there is no requirement to differentiate between left and right on the envelope. Only 'kidney' to be inscribed on the envelope.
- 20.7. The SN must document the box numbers on the organ handover sheet (**FRM4217**). A record of these box numbers must be kept by the SN 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 SN 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 SN, 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 SN must also ensure that the labelling of

all samples is correct. The SN will take final responsibility for ensuring the correct packaging of the organ and associated samples as required in readiness for handover. The SN must complete the 'Organ Packaging' section of the Donor Record.

- 21.3. The SN and OPP must seal the organ box utilising the appropriate **organ box** security sealing tape. 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/removal for handover. On these occasions the CT OPP must liaise with the SN 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 SN.
- 21.6. Documentation to accompany heart for tissue donation should be in accordance with NRC/SNBTS requirements. If QUOD biopsies are taken, the SN must document the removal of any CT QUOD biopsies on the heart valve form: **FRM4213** and in section C of SNBTS HV referral form: Heart valve retrieval checklist TCATF 451/04. If a heart is removed and packed for transplant and then declined either in theatre or at the recipient centre please refer to F-CUSTOS **SOP6549** for further guidance if there is consent for heart valve donation.

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 SN 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 SN 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	Hub Operations has responsibility to arrange transport.

Unaccompanied – Organ for other/scheduled purposes	The Researcher takes responsibility for arranging the transport.
Unaccompanied – Tissue for other/scheduled purposes	Hub Operations has responsibility to arrange transport.

- 22.3. If heart for tissue and/or research tissue is being donated for tissue and eye service (TES) research and development (R&D), the SN must contact HUB Ops to arrange transport for the collection of the heart and/or other research tissue. Transport arrangements for all tissues may be made on commencement of the retrieval and when notifying Hub Operations of knife to skin time (**SOP5024**).
- 22.4. The SN must confirm an estimated time for organ handover with the retrieval surgeons during the organ retrieval/removal process. The SN must communicate with the relevant RCPOCs, NRC/SNBTS staff and Hub Operations to ensure that transport arrangements are made in a timely manner. The SN must document any relevant communication with RCPOCs for the donor record.
- 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 SN must confirm the identity of the transport personnel for each organ being transported utilising photo ID.
- 23.2. The SN 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 SN will have completed the corresponding organ box label with the full address. No abbreviations must be used. Please refer to DAT3968-Transplant Unit Names and Addresses.
- 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 thereby documenting custody of the organ box from the SN.
- 23.5. The SN must complete the relevant sections of **FRM4217** for each organ/tissue box handed over and document their actions in the 'Sequence of Events' section of the Donor Record.
- 23.6. The research transport driver will provide the SN/OPP with three points of PID to ensure collection of the correct organ:
- ODT number
 - Organ
 - Researchers' delivery address

This will be provided to the SN by Hub Operations.

⚠ ADVICE:

The purpose of the **FRM4217** and the organ box label is for traceability of organs and supporting material such as tissue and blood samples where these are contained in a separate organ box.

⚠ ADVICE:

SNODS will hand over the appropriately packed and labelled box containing the organ to the agreed transport provider. NHSBT does not endorse the use of the police, who are not an authorised transport provider, for the movement of organs particularly if a speed exemption is taken which currently sits outside of the current road traffic regulations. The use of the police to move organs is a decision made by the accepting transplant surgeon and the SNOD should not be involved in those discussions. The decision to use the police to move organs is the responsibility of the accepting transplant centre and in these situations the SNOD may be required to handover the organ which may not be transplanted otherwise, and document in the donor file.

European travel of Organs

If any organ has been accepted by a European Country, then the below codes must be written clearly and legible on FRM4318, by the SN.

**Commodity Code 30012010 -
EORI Number GB654961603000 -**

The SN must also liaise with Hub Operations who will provide additional digits to add to the label

The SN will be prompted by Hub Operations, and IMT will not accept the organ for transport unless these codes are present.

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 and/or research, the SN must speak directly with Hub Operations to establish the potential for further delay. If the delay is longer than the anticipated SN presence in theatre, then the SN 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 SN of location and contact details.

24.1.4. The SN 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 by the person who has accepted responsibility of the organ who was identified in 24.1.3, ensuring HTA-B form is

completed.

24.2. ORGANS REMOVED FOR OTHER/SCHEDULED PURPOSES

⚠ ADVICE:

Check **SOP5567** or **SOP5663** for current guidance for the removal of organs for other/scheduled purposes (consent form research question 3a)

- 24.2.1. If organs that have been removed for other/scheduled purposes are sent to the recipient centre to await collection, the SN must inform Hub Operations that this has happened. Hub Operations will inform the researchers. Should the researchers now be unable to accept the organ, then it will be offered out via the Research Allocation System (**SOP4442**). If it is not accepted after 45 minutes the organ will be disposed of and an HTA-B Research form will be completed.
- 24.2.2. The staff at the dedicated location will be responsible for the secure accommodation and maintenance of the organ (topping up ice etc) until they are informed of the final destination (onward travel for transplant/research or disposal).
- 24.2.3. ODT Hub Operations will notify staff at the designated location when a final destination for the organ has been agreed and will arrange transport.
- 24.2.4. Staff at the designated location will then re-address the organ box as instructed by Hub Operations or dispose of the organ in line with organisational policy and complete an HTA-B Research form.
- 24.1.5 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 Lead Nurse / ODMT on call may be required.
- 24.1.6 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 SN 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 SN and the accepting centre, and an agreement with the plan. This must be clearly documented within DonorPath/the donor file. HTA-B Research form must also be completed if the organ was initially removed for other/scheduled purposes.
- 24.1.7 The SN 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 Coronal or Fiscal requests for information to be detailed. All entries to be signed and dated and a contact telephone number added as per **MPD1043**.

- 25.2 The NORS team should not be asked to delay leaving the donor hospital once they are ready to do so.
- 25.3 It is the SN's responsibility to ensure that post retrieval, The DFCS Handover **FRM5499** is completed accurately to ensure traceability and accuracy in donor family follow-up. The SN must also ensure that any ad-hoc vessels / rectus fascia retrieved is documented as per **SOP5685** on the SN to DFCS handover.
- 25.4 The SN must also update the action tracker system used in their region at the time of donation to inform ODST team on post donation follow up.

26 CARE AFTER DEATH:

- 26.1 The SN 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 SN 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 SN must always undertake the act of final care as per national guidance and local policy.
- 26.4 If local policy of the donor hospital mandates that all lines and devices must stay in situ following death/surgery, this must be documented clearly in SOE and the hospital medical notes by the SN. If the donor family are expecting all lines and devices to have been removed following surgery and the SN has been unable to facilitate this, the donor family should be made aware in immediate post donation communication. Where local policy allows and with consideration of bodily fluid leakage and structure support, the SN must aim to remove all or as many invasive lines and devices that are safe to do so.
- 26.5 The SN 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.
- 26.6 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**.
- 26.7 The SN must liaise with local theatre/portering staff to facilitate the safe transfer of the patient to the mortuary.
- 26.8 A yellow wristband with NHSBT contact details must be attached to all proceeding solid organ and tissue donors (see below). In the event a Post-mortem (PM) examination is performed, the Pathologist will contact NHSBT Hub with any suspicion of transmissible infection, tumour (or other transmissible serious disorder) that could affect the health of transplant recipient(s) and/or the patient's family

In the event a Post Mortem (PM) examination is performed, the Pathologist must contact NHSBT HUB on telephone number 01179 757 580, with any suspicion of transmissible infection, tumour (or other transmissible serious disorder) that could affect the health of transplant recipient(s) and/or the patient's family

27 LEAVING THEATRE

- 27.1 The SN 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 SN must ensure that following the organ retrieval/removal process that all external equipment and paperwork has been removed.

27.2 The SN 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 SN 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 SN must inform Hub Operations of stand down time.

28.3 The SN 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 SN 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 SN requires support in the case of non-proceeding donation, they should contact the Lead Nurse / ODMT on call for advice and guidance.

28.5 If advised by the Lead Nurse / ODMT on call the SN 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 SN must ensure their TM is aware that an incident report has been submitted as per **SOP3888**.

28.6 The SN must change the status on the Donor Record to non-proceeding explaining the reason why donation could not proceed.

28.7 The SN must also clearly document the sequence of events in the donor record, and via the DonorPath and subsequent PDA, giving clear details as to the reasons why donation could not proceed.

28.8 In the cases of a non-proceeding DCD, the SN must dispose of any blood samples as per local hospital policy and in line with **SOP5024**.

Organ Packing Guide for OPP's and SN's

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 can be clearly labelled to show which organ is being transported, and an approved NHSBT organ transport label/sticker is available.



All boxes should have a barcode label on two sides of the box which are used for identification and tracking purposes during transportation.

- *Ensure there is a barcode on two sides of the box and that they match.*
- *Ensure that the barcode number quoted on any paperwork/DonorPath is that from the side label.*

If you identify any other barcode to the lid of the box make a note of the different lid barcode number and email the number to KidneyTransportBoxes@nhsbt.nhs.uk

- *Remove the barcode label from the lid of the box and discard*

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.



2. The OPP will prepare the box lid by securing **one side** of the lid (if not already secured) with the supplied **organ box sealing tape** in the manner shown.
3. One 45cm length of tape cut into 2 pieces is adequate to seal both sides of the small organ box (image below - left).
4. Affix the organ box sealing tape from the top of the organ box, over the grey side panel and then finish fixation on the side of the organ box (image below – right).



5. The box should be prepared by the OPP in readiness for the organ being accepted from the NORS personnel. 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.



6. The prepared box will have a sample pouch for safely storing the lymph nodes, spleen and blood samples required to travel with the organ (40ml EDTA will accompany a DCD/DBD heart instead of lymph and spleen for donors over 16yrs). 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**

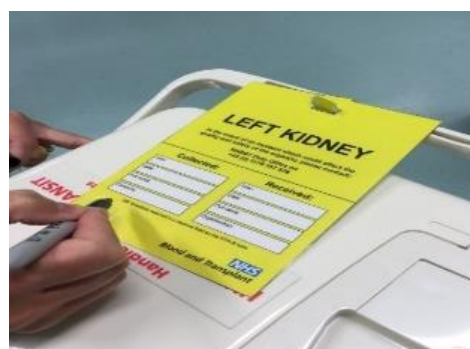
ORANGE for **ORGANS REMOVED FOR RESEARCH**

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**.

7. 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 **45cm organ box sealing tape** 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 SN 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 **organ box sealing tape** and the addresses applied to the labels once known, by the SN. 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 SN.



8. 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 SN. The last five digits on the box bar code number (after “AAA”) must be recorded on the organ handover form by the SN 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, **remove the organ box sealing tape on both sides** of the silver closing mechanisms:

Appendix A

NHSBT facilitates research and NORS Teams are required to obtain samples during retrieval for QUOD or projects agreed by Research Operation Feasibility Group (ROFG), where appropriate consent/authorisation has been obtained.

There is a potential conflict when a research biopsy (e.g. QUOD) is considered in a donor where an organ may have undergone a biopsy for clinical assessment purposes. Kidney biopsies in particular have led to governance incidents. Therefore, the SNOD and the lead surgeon must consider the following priorities specifically for **kidney biopsy**.

Priority 1.

Organ Safety Assessment.

These biopsies are obtained as there is concern relating to malignancy or other serious disease. Adequate material should be taken to secure a pathological diagnosis, excluding or confirming the diagnosis definitively. Biopsies may be wedge, punch or other as appropriate. The NORS surgeon **must discuss with recipient centres**.

Priority 2.

Organ Quality Assessment.

Biopsies are taken on the clinical request of the implanting centre for their allocated kidney to determine quality. A punch biopsy is recommended. Only one quality assessment biopsy should be taken from that kidney. A quality assessment biopsy may be taken in addition to an organ safety assessment biopsy (Priority 1), if deemed necessary and **requested** by the recipient centre.

Priority 3.

QUOD Biopsies.

QUOD (research) biopsies should only be taken if **no other biopsies are requested or taken**. Only one attempt should be made to take a QUOD biopsy, and only one QUOD biopsy should be taken from a kidney.

*For the avoidance of doubt, if a biopsy has been taken for organ safety and/or organ quality, **a further research biopsy must not be taken**.*

Useful Information

1. Associated Documents

POLs:

POL173 - Infection Prevention and Control in NHSBT

POL188 - Clinical contraindications to Approaching Families for Possible Organ & Tissue Donation

MPDs:

MPD845 - Family Care

MPD881 - Findings Requiring Additional Action

MPD889 - Abdominal Perfusion and Preservation

MPD865 – Obtaining Coroner/Procurator Fiscal Decision

MPD891 - Establishing Pregnancy Status and Pregnancy in Donation

MPD1043 - National Standards for Organ Retrieval from Deceased Donors

MPD1100 - Guidance and Principles - Donor Related Images and Video

MPD1382 – Donation Pathway Communication Touchpoints- SNODs and Hub Operations

MPD1682 - Offering Deceased Donor Organs to Republic of Ireland / Europe

SOPs:

SOP5024 - Tissue Referral Process

SOP3888 - Reporting an Organ Donation or Transplantation Incident to NHSBT

SOP4574 - Logistics & 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

SOP4746 - DCD Heart Donation Process

SOP4938 – Sharing Clinical Information

SOP5352- Findings During Retrieval Requiring Histopathology Assessment

SOP5567 - Process for Consent for Removal and Storage of Organs/Tissue/Samples for Research and Other Scheduled Purposes in QUOD Licensed Hospitals Only

SOP5663 - Process for Authorisation for the Removal and Storage of specific Organs/Tissue/Samples for Research and Other Purposes within Scotland

SOP5685 - Ad-hoc Tissue Requests of Blood Vessels and Rectus Fascia from Deceased Organ Donors

SOP5917- Abdominal NRP

SOP6496 – SENTINEL Trial

SOP6549 – F-CUSTOS study

INFs:

INF1424 - Basic Guidelines for Theatre Staff at Donor Hospital

INF1425 - Care of Potential Lung DCD Donors – Safety Brief

FRMs:

FRM4121 - Kidney Donor Information

FRM4122 - Deceased Donor Pancreas Information

FRM4131 - DCD Observation Chart

FRM7307 – Organ Retrieval Safety Checklist

FRM4153 - Proceeding and Non-Proceeding Donors after Circulatory Death

FRM4212 - Organ Donation Clinical Pathway

FRM4213 - Heart Valve Donation
FRM4217 - Organ Handover Form
FRM4318 - Organ Box Address Sticker
FRM5499 - SN to DFCS Handover Form
FRM5867 - National Histopathology Request Form
FRM6199 - Vessels Form
FRM6723 - Sample Form

DATs:

DAT3968 - Transplant Unit Names and Addresses

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

ODT Clinical Website

<https://www.odt.nhs.uk>

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: Guide to the quality and safety of organs for transplantation

<https://freepub.edqm.eu/publications/PUBSD-88/detail>

Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations).

<https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/material-covered-human-tissue-quality>

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 NHSBT accounts or between NHSBT to [nhs.net](https://nhs.uk) and between [nhs.net](https://nhs.uk) accounts.

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

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.

DFCS- Donor Family Care Service

CLOD – Clinical Lead Organ Donation.

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

ED – Emergency Department.

ODR – Organ Donor Register.

ODST – Organ Donation Services Team.

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

OPP – Organ Preservation Practitioner.

NHSBT approved scanning application - an IPAD application approved for use with NHSBT authorised IPADS.

ODMT On Call – Escalation to Organ Donation Management Team.

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.

INOAR – Increasing Number of Organs Accepted for Research

Medical Practitioner – facilitates the WLST process.

NHSBT – NHS Blood and Transplant.

NORS – National Organ Retrieval Service.

NTLC – National Transplant Liaison Co-ordinator.

Lead Nurse – Operation lead for Organ Donation Service Team.

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.

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

SN – (Specialist Nurse) - for the purposes of this document the terminology ‘SN’ will apply to Specialist Nurse in Organ Donation, and SR (Specialist Requestor) whom have the relevant knowledge, skills and training in organ donation, working within NHSBT Organ Donation Services Teams (ODST).

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.

Document Details:

Document Title	< Theatre Manual for Deceased Organ Donors >	
Document Number & Revision Number	<12>	
Type of Change	Change to Existing Process>	
Stakeholders who require training	Trainee new to the process	Trainee trained to the previous revision.
	<New trainee SNs will require full training to this document by their ODST Quality Lead SN and Foundation Training programme.>	SNs previously trained to sOP5499 versions before this version 12, can receive training via recorded author presentation delivered by their regional Quality Lead SN.>
Knowledge required prior to training	,<Full training through of SOP with PDS and Quality Lead SN>	<Trained to previous version.>
Critical aspects of process	<p>< This document aims to assist the SN in organising the organ retrieval/removal operation. It will outline the SN'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.</p> <p>This document outlines the joint responsibilities of the SN and OPP regarding the entire retrieval/removal process. The document will outline the SN'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.</p> <p>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. ></p>	

Training Plan:

	Trainee new to the process	Trainee trained to the previous revision.
Recommended Training Method	<p>< Practical demonstration and read through the document with Regional ODST Quality Lead.</p> <p>Training material for this version will not cover the whole SOP content.></p>	<p><Train out via standardised video from SOP Author to ODST Regional Quality Leads train to TBTR.</p> <p>The same video can be disseminated via QLS and record TBTRs></p>
Assessment	<p>< TBTR Training Record ></p> <p>•</p>	<p>< TBTR Training Record></p> <p>•</p>

Cascade Plan	<p>< Practical demonstration and read through the document with Regional ODST Quality Lead.</p> <p>Training material for this version will not cover the whole SOP content.></p>	<p>< Train out via standardised video from SOP Author to ODST Regional Quality Leads train to TBTR.</p> <p>The same video can be disseminated via ODST QLs and record TBTRs></p>
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Training Score – Training Plan Risk Matrix (Collapsible – Click ► icon to open/close)

Use the *Training Plan Risk Matrix* to identify the training method and assessment required.

The *Process Criticality Score* is determined by the potential impact on donor/patient safety and/or product quality using the table below for guidance.

	Impact on Donor, Patient safety or product quality
1. Negligible	A process whose failure, in full or in part, cannot impact product quality, patient/donor safety or the ability to supply products/services.
2. Minor	A process whose failure, in full or in part, may : <ul style="list-style-type: none"> (i) impact other processes thereby indirectly impacting product quality, patient/donor safety (e.g. harm only results where multiple failures in multiple processes align) (ii) result in the discard of a small number of replaceable products and/or (iii) result in an inconvenient delay to the supply of products/services (e.g. delay of 1-3hrs of non-urgent product/service).
3. Moderate	A process whose failure, in full or in part, may : <ul style="list-style-type: none"> (i) indirectly impact product quality, patient/donor safety (e.g. harm only results where failures in more than 1 process align) (ii) result in the discard of a medium number of replaceable products and/or (iii) result in a temporary delay to the supply of products/services (e.g. delay of 4-12hours of non-urgent products/services).
4. High	A process whose failure, in full or in part, is likely to: <ul style="list-style-type: none"> (i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.
5. Very High	A process whose failure, in full or in part, is certain to: <ul style="list-style-type: none"> (i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.
Process Criticality Score	<2>

The *Criticality of Change Score* is determined by assessing the nature of change(s) and complexity of the process using the table below for guidance.

	Change to Trainee(s)
1. Negligible	An existing process to which no material changes are made. E.g. format changes, minor clarifications of existing practice, fixing typos.
2. Minor	An existing process to which new information is added but where changes to existing knowledge and practices are minimal. E.g. clarifications that tighten existing practices
3. Moderate	An existing process of low complexity with material changes requiring different people to take action and/or people to change the tasks they perform. E.g. new roles/responsibilities, changes to the order of existing tasks, new tasks
4. High	A new process of moderate complexity, OR An existing process of moderate complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
5. Very High	A new process of high complexity, OR An existing process of high complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
Criticality of Change Score	<2>

Training Plan Risk Matrix:

		Process Criticality				
		1. Negligible	2. Minor	3. Moderate	4. High	5. Very High
Criticality of Change	1. Low	1	2	3	4	5
	2. Moderately Low	2	4	6	8	10
	3. Moderate	3	6	9	12	15
	4. High	4	8	12	16	20
	5. Very High	5	10	15	20	25

Controlled if copy number stated on document and issued by QA

(Template Version 06JAN2025)

	Trainee new to the process	Trainee trained to the previous revision.
Process Criticality Score	<2>	
Criticality of Change Score	<2>	<2>
Training Score	<4>	<4>

Recommended Training Method:

Training Score	Level of Risk	Examples of Training Methods	Examples of Assessment
1 - 3	Low	Read only	Record on FRM511 only
4 - 8	Manageable	Email, team brief, word brief	Knowledge/Observation Check & FRM511
9 - 14	Medium/Significant	Formal training package	Knowledge/Observation Check & FRM511 or FRM5076
15 - 25	High	Practical	FRM5076 or equivalent