

OTDT Manual 5: Managing and Sharing Clinical Information

Restrictions

This Manual is to be utilised by qualified and trained Specialist Nurse (SN). If the SN is in training, this Manual is to be utilised under supervision. In the circumstance of requiring additional support or guidance please escalate to an appropriate colleague, such as a Lead Nurse (LN) or Organ Donation Leadership Team (ODLT).

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Summary of changes

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SUMMARY OF CHANGES

Process changes:

- References to MPD881, SOP5352, MPD882, SOP5735 and MPD867 removed as they are now sections of this document (SOP4938 v10) and respective new process documents and locations amended.
- Addition of **MPD1043** 'National Standards for Organ Retrieval from Deceased Donors', **SOP5499** 'OTDT manual 4: Offering and **FRM4193** 'Core Donor Data - SNOD (Used as EOS back-up)' as related documents.

OTDT Manuals Project:
The following obsolete SOPs have now been merged into this new single manual (SOP4938 v10) and trained processes are defined by sections:

Introduction:	Amalgamation of objectives and purposes content from multiple sections of SOP4938, MPD881, SOP5352, MPD882, SOP5735 and MPD867.
Section 1:	Key principles of practices amalgamated from multiple sections of SOP4938, MPD881, MPD882, MPD887 and SOP5735.
Section 2:	Full integration of remaining MPD867 process.
Section 3:	Integration of MPD881 section 4 as phase of donation managing and sharing clinical information.
Section 4:	Integration of MPD881 section 5, adding managing additional findings alongside sharing clinical information.
Section 5:	Integration of MPD881 section 6, adding managing additional findings alongside sharing clinical information.
Section 6:	Integration of MPD881 section 7, adding managing additional findings alongside sharing clinical information.
Section 7:	Integration of MPD881 section 8, adding managing additional findings alongside sharing clinical information.
Section 8:	Full integration of remaining SOP5352 process.
Section 9:	Full integration of remaining SOP5735 process.
Section 10:	Full integration of remaining MPD882 process.
Section 11:	Integration of MPD881 section 2 regarding Statutory Notifiable Diseases.
Section 12:	No changes to Hub Operations process, only changed document references where impacted.

Removals Summary

- Reference to MPD1131 removed as obsolete in 2024.
- Reference to FRM1602 removed as obsolete in 2026.
- FRM4212, INF947 and MPD1382 removed from associated documents.
- MPD881, SOP5352, MPD882, SOP5735 and MPD867 will become obsolete on the effective date of this document (SOP4398 v10).

INTRODUCTION

This manual's purpose is to ensure clear, effective, and timely communication of new clinical information across Specialist Nurse (SN) and Hub Operations functions.

To minimise risks associated with organ and tissue transplantation, all known or newly identified clinical findings must be assessed immediately and communicated without delay. During the deceased donation process, multiple receiving centres may be involved, including Transplant Centres, Tissue Banks, Islet and Hepatocyte laboratories, and Research Banks. In some cases, organs or tissues initially retrieved for research may later be considered for transplantation.

Following clinical assessment, receiving centres (Transplant Centres, Tissue Banks, and Research Banks) may still accept organs or tissues based on a risk-benefit analysis completed by the implanting surgeon or relevant tissue/research representative. The role of the SN and OAS is to ensure that all new information is shared promptly, accurately, and through the correct communication pathways.
The purpose of this manual is to define a clear communication process for SNs and OAS regarding the assessment and escalation of any new clinical information identified at any stage of the donation process. It is essential that all receiving centres are notified as soon as possible and that, where required, the SN leads the clinical discussion.

New clinical information may arise at any point, from referral through to post-implantation. In all instances, new findings must be considered within the appropriate clinical context, with attention given to the wider impact on all receiving centres that have received - or may receive - organs or tissues from the same donor.

STOP - PAUSE - CHECK

On all occasions colleagues must employ the **STOP PAUSE CHECK** approach to ensure that all information is assessed and shared in the safest way possible.

When new clinical information is identified, the SN is responsible for ensuring that this information is communicated to all relevant receiving centres, including any centres currently considering an organ or tissue offer. The SN will determine and agree the appropriate communication method with the OAS, in line with the processes outlined in this manual. The SN is accountable for confirming that all required communication has been completed and that every receiving centre has been informed.

When information is to be shared with Hub Operations for dissemination to centres, the following email address must be used: **odthub.operations@nhsbt.nhs.uk**.

When Hub Operations needs to provide information to an SN, this may be sent to the Regional SN Team email address. However, Hub Operations must follow up with a telephone call to confirm that the information has been received and is being acted upon appropriately.

PATIENT SAFETY INFORMATION:
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 OTDT Directorate of NHSBT using the following link: https://safe.nhsbt.nhs.uk/IncidentSubmission

RESPONSIBILITIES (A-Z):

- **Donor Family Care Service (DFCS) –** Ensures additional clinical information received via Hub Operations, GP's or Microbiology labs is shared with the lead SN at the earliest opportunity and uploaded to DonorPath with actions noted in sequence of events in line with **SOP5049 OTDT Manual 8**.

- **External Tissue Banks** – Are responsible for the retrieval, processing, storage and allocation and release of tissue under the Tissues and Cells Regulations.

- **Histopathology Laboratory** – Notify SN/Hub Operations of any findings or results following histopathology assessment.

- **Implanting Surgeon** - Is ultimately responsible for the decision to accept and transplant a donated organ.

- **Lead Nurse (LN) / ODLT On-Call –** To provide support to SN as required and provide support to the SN as required and oversee regional system for follow-up and action of all outstanding results in a timely way ensuring the safety of recipients is paramount. The escalation sequence for management support:
    - Lead Nurse
    - Geographical Regional Head of Nursing (if available)
    - ODLT On-Call member (out of hours or if geographical RHoN not available)

- **Medical Practitioners** - To confirm finding (s) requiring additional action with the SN and to facilitate expert practitioner advice, where required. Medical Practitioners have a statutory responsibility to notify if they suspect one of their patients has an infectious disease from the list detailed in the Statutory Notifiable Diseases **INF958** (England & Wales), **INF960** (Scotland) and **INF961** (Northern Ireland).

- **National Organ Retrieval Service / Lead Surgeon** - Is responsible for reporting any finding (s) requiring additional action during the retrieval procedure to the SN for action as per this manual and **MPD1043**. To also complete all relevant clinical information on National Request Form (**FRM5867**).

- **Organ Allocations Specialists (OAS)** – Record all information accurately on NTxD ensuring clear communication with SN and agreement of communication cascade as per flowcharts contained within this document.

- **Receiving Centres / Recipient Centre Point of Contact (RPoC) –** Encompassing Transplant Centres, Tissue Banks, Islet and Hepatocyte Processing Laboratories, and Research Banks, the RPoC must notify the transplanting surgeon (following local centre procedures) of any findings requiring additional action, along with information provided by the Specialist Nurse (SN). This applies during all stages of organ or tissue offer consideration - both before and after receipt of the organ/tissue. Receiving Centres are responsible for reviewing the Core Donor Data (CDD) via TransplantPath to assess all relevant clinical information (**FRM4197** Core Donor Data - SNOD (Used as EOS back-up)). Centres must contact Hub Operations at the earliest opportunity to ensure an SN is available to discuss the findings, provide clinical context, and agree on a communication plan. This manual and **FRM6390** must be used where histopathology is required. Where an organ is received with the intention of being transplanted as tissue, the Receiving Centre is responsible for reviewing all available information prior to release, in accordance with the Tissues and Cells Regulations.

- **Research Banks** - Responsible for the processing, storage and allocation of organs / tissues retrieved for research – all details available via **DAT4135.**

- **Specialist Nurses (SN)** – To provide clinical insight and to communicate, report and document any new clinical information and ensuring that it is shared with Hub Operations at the earliest opportunity giving clear advice on any plan of action. SN to utilise **Findings During Retrieval Requiring Histopathology or Microbiology Assessment** for any lesions identified during retrieval that may require assessment and histopathology completing the National Histopathology Request Form (**FRM5867**). SN to take responsibility for ensuring all receiving centres are contacted with regards to new clinical information, voice recording any clinical conversations utilising **SOP6651 OTDT Manual 11**. SN also responsible for ensuring all outstanding and final results are followed up post donation. Responsible for escalation to Lead Nurse / Regional Head of Nursing / ODLT On-Call should they or an SN colleague be unable to action immediate request.

1. PRINCIPLES OF MANAGING AND SHARING CLINICAL INFORMATION

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1.1	New Clinical Findings
1.2	Receiving Centres
1.3	Clinical Information that DOES NOT REQUIRE Further Clinical 'Explanation'
1.4	Clinical Information that DOES REQUIRE Further Clinical 'Explanation'
1.5	Transfer of Clinical Information onto DonorPath
1.6	Documentation / Record of Information
1.7	Email Security Guidance
1.8	Final Actions Required by SNs Before Closure of Donor File by DFCS
	Associated Documents and References (A-Z)

1.1. NEW CLINICAL FINDINGS

1.1.1. For this manual, new clinical findings are defined as any unanticipated discovery made at any stage of the deceased organ donation or transplantation process. These findings must be reported and documented so all relevant parties are informed, and appropriate actions can be taken to maintain safety. This includes any results or observations that may impact the safety or effectiveness of donation or transplantation. For example:

a) Potential adverse outcomes for the recipients that are not anticipated, for example donor-derived malignancy or some donor-derived infections.
b) Donor information established post donation/transplantation which may have consequences for recipients.
c) Adverse incidents resulting in the non-transplantation of suitable donor organ(s) or reduction in the quality of organ(s).
d) Serious injury to the organs, such as major vascular injury or physical damage to the organ.
e) Suboptimal organ packing, compromising cold storage, for example lack of ice, insufficient packing solution, inappropriate organ containers or defects.
f) Statutory Notifiable Disease (**INF958** (England & Wales), **INF960** (Scotland) and **INF961** (Northern Ireland)).

1.1.2. To reduce associated risks with organ and tissue transplantation, all unknown or previously unknown findings must be clinically assessed immediately and communicated. Organs and tissues may still be accepted following clinical assessment based on a risk benefit analysis undertaken by the implanting surgeon or tissues representative.

1.1.3. Information on findings requiring additional actions must be clearly visible to Receiving Centres by inputting the data in a visible section of the CDD (indicated with a Wi-Fi symbol). Specific areas must also be used for significant findings from donor theatre and post donation – such as the specific 'Organ Retrieval / New significant clinical information' box, within the 'Retrieval Information' section of DonorPath.

1.1.4. There are several points during the donation process that additional findings can be identified in the differing phases of donation and transplantation.

1.1.5. It is essential that in all circumstances these additional findings must be clearly communicated with **ALL** relevant parties.

1.2. RECEIVING CENTRES

1.2.1. When considering the receiving centres, it is the responsibility of the SN to ensure every receiving centre is communicated with in either phase of organ/tissue offer consideration, acceptance before receipt of the organ/tissue or after receipt of the organ/tissue. Consideration must be given, but not limited, to the following applicable receiving centres:

- Organ specific Transplant Centres
- Pancreas Islet Banks/Laboratories
- Liver Hepatocyte Processing Banks
- Liver Vessel Banks (liver vessels may be stored or may have been transplanted into a different patient)
- Novel grafts – limbs, rectus fascia, uterus, face etc.
- Centres receiving ad-hoc tissues (ad-hoc vessels or ad-hoc rectus fascia) as per **SOP5685**
- National Referral Centre (NHS Blood and Transplant)
- Scottish National Blood and Tissue Services (SNBTS)
- Research Banks (excluding QUOD)
- Donor Family Care Service (addition to Donor File)

1.2.2. For all deceased organ donors, the SN is responsible for ensuring that all receiving centres are informed of any new clinical information. Using the pathways in this document, the SN can work with the OAS to do this. As external centres do not have access to DonorPath and view all offers and updates through TransplantPath, any information that must be shared must be recorded in the visible sections of DonorPath. .

1.2.3. In all cases, ALL receiving centres must be fully considered in the context of the information to be shared and the timeframes / urgency associated. Communication must take place with receiving centres (Transplant, Tissues or Research) and all processing centres (for example tissues and hepatocytes/islets) to maintain the quality and safety of organs and tissues.

1.3. CLINICAL INFORMATION THAT DOES NOT REQUIRE FURTHER CLINICAL 'EXPLANATION'

1.3.1. Maintaining haemodynamic stability in donor care requires regular review of all aspects of the patient's status. Whenever new clinical information arises, the SN must decide whether it requires further contextual explanation to receiving centres or other stakeholders and determine the most appropriate method for doing so.
Examples of new clinical information that does not require additional clinical explanation may include, but are not limited to:

- Updated Arterial Blood Gases within acceptable parameters
- Updated blood results which are within normal parameters
- Availability of outstanding Echocardiogram report

These updates can be recorded on DonorPath by the SN whose responsibility it is to notify the OAS asking them to communicate to receiving centres that an update is available.

1.4. CLINICAL INFORMATION THAT DOES REQUIRE FURTHER CLINICAL 'EXPLANATION'

1.4.1. There are more specific examples that for the purposes of this manual require the SN to communicate directly with receiving centres or those centres considering an organ offer. Examples of new clinical information that requires clinical 'explanation' include:

- New clinical information resulting from General Practitioner (GP) Assessment

- Unexpected finding at bedside patient top to toe assessment
- Unexpected finding at retrieval
- Positive microbiology
- Unexpected vasculature on organ retrieval with implications for an accepting centre
- Significant deterioration or improvement in organ function which may impact on organ offers including receiving centres who may have expressed an interest, such as:
  - Deterioration in Arterial Blood Gases from those previously on DonorPath
  - Trans Oesophageal Echocardiogram / cardiac output studies pre retrieval impacting on acceptance of cardiothoracic organs.

1.5. TRANSFER OF CLINICAL INFORMATION ONTO DONORPATH

1.5.1. RPoC's are reliant on the information communicated to them by SN's when ascertaining donor suitability and recipient selection. The sharing of this information is time critical in support of their decision making.

1.5.2. Data is pushed and shared between the systems (DonorPath, TissuePath and TransplantPath) at the point of a status change. Details of the specific functionality and data sharing between the Path suite can be found in **SOP6651 OTDT Manual 11.**

1.5.3. It is the SN's responsibility to ensure that any new information which comes to light at any stage during the deceased donation pathway is shared with the receiving centres, as per relevant sections of this manual.

IMPORTANT NOTE FOR SPECIALIST NURSES

The Wi-Fi symbol in DonorPath represents sections which are visible to Receiving Centres in the Core Donor Data (CDD). Information entered in sections without this symbol CANNOT be seen by Recipient Centres.

Updates to DonorPath during and after the point of offering must include a date and time as part of the update to the CDD in any visible section of DonorPath (e.g. *Update 1/1/25 0800: There is new inf...*)
If there is insufficient character space on DonorPath to complete this, ensure receiving centres are clearly informed on the specific location of update within CDD.

TransplantPath users can also upload files and organ media to support organ/tissue assessment at the Receiving Centre. However, **only added files will be visible on DonorPath and TissuePath; organ media will not transfer back to DonorPath and remain visible only to TransplantPath users.** TransplantPath users are responsible for informing Hub Operations and/or the SN whenever new information is added to the digital donor record to commence sharing of clinical information.

If DonorPath and/or TransplantPath are unavailable, the SN must follow the manual process as outlined in SOP6651 OTDT Manual 11.
Due to IT restrictions and secure systems, it is often not possible to send scans/x-rays/reports from one Hospital Trust to another. These should be sent as per guidance outlined in **SOP6651 OTDT Manual 11** relating to Personal Identifiable Data. Where DonorPath functionality allows, information should always be shared via the DonorPath application making it directly visible on TransplantPath

Voice recording should be used for all clinical conversations, follow SOP6651 OTDT Manual 11

1.5.4. It is the responsibility of the SN / Regional Organ Donation Team to follow-up any outstanding final results (in addition to interim results). If this involves direct engagement with the receiving centre or the centre performing the histopathology, it is the SNs responsibility to do this.

1.6. DOCUMENTATION / RECORD OF INFORMATION

The SN must document all relevant conversations with the Medical Practitioner, Expert Practitioner in Public Health, and other Healthcare Professionals in both the patient's medical record and DonorPath. All entries must be signed and dated. Guidance on good documentation is provided in **MPD385**, with examples available in **DAT4183**.

1.6.1. The SN must document, as reported, all the information regarding the finding in the patient's medical records and scan the document with the NHSBT approved scanning application for entry into the donor file.

1.7. EMAIL SECURITY GUIDANCE

1.7.1. When sending any email outside of NHSBT that contains donor information - even if the recipient is another NHS organisation - the sender must apply the **OFFICIAL-SENSITIVE** label under the **CLINICAL** category. When any reference is made through this document with an action requesting information be emailed, the sender must apply this principle.
Note: This action can only be performed using Microsoft Outlook on Desktop or the Outlook app.

1.7.2. Detailed instructions are available in the NHSBT Office 365 Knowledge Base article:
a) Click the following link: https://nhsbt.service-now.com/sp?id=ict_services
b) Search for: **How to send confidential emails with sensitive content**

1.7.3. Once the email is sent, there is no requirement to issue a password to the recipient. The system automatically manages authentication requests where necessary.

This ensures compliance with information security standards (DCB1596: Secure email). This information standard defines the minimum non-functional requirements for a secure email service, covering the storage and transmission of email, including where email is used for the sharing of patient identifiable data, published under section 250 of the Health and Social Care Act 2012.

1.8. FINAL ACTIONS REQUIRED BY SNs BEFORE CLOSURE OF DONOR FILE BY DFCS

1.8.1. The DFCS is responsible for ensuring the GP Medical Report for Organ and Tissue Donation **FRM6342** is returned and uploaded to DonorPath as per **SOP5049 OTDT Manual 8.**

1.8.2. The SN is responsible for ensuring that clinical information contained in **FRM6342** is checked against the information documented on DonorPath under Patient Assessment or on the Medical and Social History (MaSH) form (**FRM4211**).

1.8.3. The SN is responsible for following up all known microbiology and biopsy samples submitted by the organ donation team for donor assessment, as well as any outstanding results at the time donation proceeds. All regional organ donation teams must have systems in place to ensure timely follow-up with donating hospitals. Examples include, but are not limited to:
a) Blood cultures (inclusive of any sent at donor hospital as part of DCD heart programme or in relation to ANRP)
b) Sputum samples
c) Urine samples
d) Outstanding histopathology performed at donor hospital

2. PATIENT INFORMATION COMMUNICATED TO RECIPIENT CENTRE POINTS OF CONTACT

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2.1	Collaborative Responsibilities
2.2	Key Information to be Communicated to all Recipient Centres
2.3	Communication to Recipient Centre Points of Contact
	Associated Documents and References (A-Z)

The SN is responsible for obtaining a comprehensive medical, behavioural, social, and travel history using the processes in this policy, and for documenting all findings in the visible sections of DonorPath so they appear on TransplantPath. Relevant information must also be communicated directly to recipient points of contact.

2.1. COLLABORATIVE RESPONSIBILITIES

To ensure an accurate history, the SN must obtain a clear account of the donor's admission, illness, and diagnosis from clinical staff, and review all available electronic and paper medical records. Where additional records may exist, reasonable efforts must be made to locate them.

2.1.1. The SN must contact the donor's GP in line with **SOP6405 OTDT Manual 1** and, where applicable, other professionals involved in the donor's care (e.g., drug and alcohol services, social workers, carers, community nurses, care home staff). If these contacts cannot be reached out of hours, they must be followed up the next working day. All information must be documented in DonorPath, and any verbal updates provided to recipient teams must be voice recorded in accordance with **SOP6651 OTDT Manual 11.**

2.1.2. A family interview must be conducted to complete the MaSH questionnaire (**FRM4211**), using the most appropriate person due to the sensitivity of some questions. Any disclosures requiring clarification should be followed up. The SN must also complete a full physical assessment, including a body map (**FRM5545**) as per **SOP6405 OTDT Manual 1**, and record all findings in DonorPath before registration with ODT HUB Operations.

2.1.3. Any new clinical information arising at any stage must be shared in line with this manual. Information intended for recipient centres must be entered only in DonorPath sections marked with the Wi-Fi symbol, as these are visible on TransplantPath. Notes written on behalf of the SN must be recorded in the DonorPath Sequence of Events to ensure full traceability under the Quality and Safety of Organs Intended for Transplantation Regulations 2012.

2.1.4. The SN must also inform recipient contacts of any unavailable information at the point of donor characterisation, such as pending results or additional medical records. All outstanding results known at the time of donation must be followed up post-donation, with documentation and voice recording as required.

ⓘ ADVICE

The Wi-Fi symbol in DonorPath represents sections which are visible to Recipient Centres. Information entered in sections without this symbol CANNOT be seen by Recipient Centres.

2.2. KEY INFORMATION TO BE COMMUNICATED TO ALL RECIPIENT CENTRES

In addition to the information listed above, consideration must be given to providing the recipient centre points of contact with a detailed medical, behavioural, social and travel history. This is ensured by documenting all relevant information on the visible sections of DonorPath, making this visible on TransplantPath. Guidance is offered in the list below:
The following is not an exhaustive list:

- Re-confirm Blood Group
- Diagnosis/Cause of Death (If Hypoxic Brain Injury detail mechanism of injury)
- If cardiac arrest- include all details such as length of 'down time', drugs received and whether in-hospital or out-of-hospital arrest, detailing whether bystander or medically trained professional performing Cardio Pulmonary Resuscitation (CPR).
- If Bacterial Meningitis state start time of first dose of antibiotics, if Encephalitis detail presentation/travel history
- Detailed Past Medical History (PMH)
  - Cancers –detail the type, grade, date of diagnosis, prognosis, evidence of spread and treatment given, information contained in follow up letters and Consultant details. SN may need to discuss the history with the patients Consultant Oncologist to ascertain possibility of transmission. A follow up conversation may be undertaken by the transplanting surgeon as necessary.
  - Details of Investigations undertaken and follow up received (if follow up not yet received, document clear timelines / expected timeline of results on DonorPath). Known outstanding results must be followed up by the SN post donation.
  - Previous hospital admissions of significance
  - Unexplained weight loss
  - Physical description of patient appearance in addition to height, weight and BMI, for example very large abdomen/muscular, amputee or wheelchair bound
  - Hypertension defined as a systolic pressure above 140 with a diastolic pressure above 90
  - Hypercholesterolemia when diagnosed, details of medication and compliance if known
  - Sepsis whether of known or unknown aetiology and details of treatment given and response to treatment
  - History of organ disease/injury/failure
  - Previous/recent surgery
  - Current and past 3 months- precise medications including compliance, dose, length of time being taken and for what reason
  - History of illicit drug use and details
  - History of confirmed/unconfirmed H1N1 / COVID-19 risk utilising **FRM6439** or any other flu-like symptoms where applicable
- Include microbiology results. Any additional specimens sent by the SN/unit or known about at the time of donation must be documented on DonorPath and results followed up post donation and tracked by local SN team.
- Biopsy results-including information regarding planned biopsies post mortem for example an undiagnosed brain tumour. These results must be followed up by the SN post donation.
- All blood results taken as per **SOP6405 OTDT Manual 1** must have final results followed up as per **SOP6514 OTDT Manual 3**.
- CT Scan results/reports (record who is providing the information radiologist or neuro radiologist)
- Any significant changes in haemodynamic status must be communicated
- Method and location for withdrawal of treatment (DCD donors)
- Social and Family History:
  - Familial history-significance of hereditary diseases/rare conditions which the donor may be at risk of and subsequent transmission to the recipient.

2.3. COMMUNICATION TO RECEIVING CENTRES

2.3.1. Recipient centre points of contact are reliant on the information communicated to them by SNs when ascertaining donor suitability and recipient selection. It is the SN's responsibility to document all of the information obtained from the MaSH Questionnaire **FRM4211**, physical assessment **SOP6405 OTDT Manual 1**, GP Medical Report **FRM6342**, body map within **FRM5545**, key information outlined in section 3 and a review of the medical records (both hard copies and electronic) accurately onto visible sections of DonorPath, making this visible on TransplantPath.

2.3.2. In circumstances where it is not possible to record all the information obtained onto DonorPath or there is a requirement to discuss information verbally with the recipient point of contact, the SN must ensure that all clinical communication is voice recorded as per **SOP6651 OTDT Manual 11**. ODT HUB Operations must also be made aware of the information being communicated verbally directly between the SN and recipient point of contact.

2.3.3. In circumstances that require the SN to communicate key clinical information verbally with the recipient centres, for example regarding a biopsy report, this must be undertaken as per Findings During Retrieval Requiring Histopathology or Microbiology Assessment and all clinical conversations must be voice recorded as per **SOP6651 OTDT Manual 11**.

2.3.4. The SN must document all communications in DonorPath Sequence of Events (SoE) including with whom the conversation took place and the information shared. Any clinical information of relevance to recipient centres must be documented within the visible sections of DonorPath (Sequence of events is only visible to the SN).

2.3.5. The SN is responsible for follow-up of all known microbiological and biopsy samples sent by the organ donation team for the purposes of donor assessment or any relevant samples that remain outstanding at the time of donation proceeding. All Regional organ donation teams must have systems in place to ensure that results are followed up in a timely manner with the donating hospitals.

2.3.6. In circumstances where results are outstanding and/or new clinical information comes to light during the deceased donation process it is the responsibility of the SN to follow relevant sections of this manual to enable a structured approach to clinical information sharing to all receiving centres and follow-up of final results.

2.3.7. It is the responsibility of the recipient centre point of contact to document and share information with the retrieving / implanting surgeon as per locally agreed policies.

3. NEW CLINICAL INFORMATION POST CONSENT / AUTHORISATION AND PRE DONOR REGISTRATION

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3.1	Findings Requiring Additional Action
3.2	Sharing Clinical Information
	Associated Documents and References (A-Z)

3.1. FINDINGS REQUIRING ADDITIONAL ACTION

Following consent/authorisation and pre-donor registration with HUB Operations, if the SN identifies a finding requiring further action, they must inform and discuss this with the treating Medical Practitioner to assess any implications for donation safety and quality.

3.1.1. The SN must confirm with the Medical Practitioner whether expert advice is required and whether any additional medical records exist that may reveal further undisclosed medical history.

3.1.2. The SN may only stop the donation process if, in agreement with the treating Medical Practitioner, an absolute contraindication to donation is identified in line with **POL188**. If a ODT donor number has been generated on DonorPath and the donor case is standing down before donor registration, the SN must inform Hub Operations to alert them that the donation case will not progress to support national planning.

3.1.3. If an absolute contraindication is confirmed, the SN should use the relevant procedural document to guide communication with the patient's family and escalate to LN/Regional Head of Nursing/ ODLT On-Call if needed.

3.1.4. Where a Medical Examiner, Coroner, or Procurator Fiscal is involved, the SN must inform them of the decision not to proceed, following local policy agreements with regional ODST.

3.2. SHARING CLINICAL INFORMATION

3.2.1. If a new clinical finding is identified that is not an absolute contraindication, the SN must discuss with the treating Medical Practitioner whether further expert advice is required. The SN must promptly document all information on DonorPath, including uploading relevant reports and ensuring visibility on TransplantPath before donor registration and offering.

3.2.2. Any real-time discussions held in the presence of the family must be recorded in DonorPath.

3.2.3. If all relevant information cannot be recorded in the visible sections of DonorPath, the SN should add a note in the general comments section stating that further details are available via HUB Operations.

3.2.4. If the donor process is stood down, the SN must use Communicating with Families about Findings Requiring Additional Action section to support discussions with the family. This communication should be undertaken with donating hospital staff. The SN may seek support from the ODS Team, Regional management, or the ODLT On-Call.

3.2.5. If appropriate, the SN must complete an NHSBT Clinical Governance Form at the earliest opportunity to ensure the finding is recorded and managed. Any relevant supporting documentation should be attached.

4. NEW CLINICAL INFORMATION POST REGISTRATION BUT PRE - RETRIEVAL

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4.1	Findings Requiring Additional Action
4.2	Sharing Clinical Information
	Section Procedural Diagram
	Associated Documents and References (A-Z)

4.1. FINDINGS REQUIRING ADDITIONAL ACTION

4.1.1. After consent/authorisation and donor registration, if the SN identifies a potential new finding, they must discuss it with the treating Medical Practitioner to understand the implications for donation safety and quality. The SN is required to seek expert advice and whether any additional medical records exist that may reveal undisclosed medical history. Any discussions held with the family about the consequences of the finding or investigating the finding must be recorded on DonorPath.

4.1.2. Donation should only be stopped if the SN and medical team jointly identify and confirm an absolute contraindication according to **POL188**. If the donor process is stood down, the SN must follow the relevant procedure for communication with the family, working with hospital staff and inform Coroner / Procurator Fiscal of events if applicable.

4.1.3. If a new finding **does not** meet **POL188** absolute contraindication criteria, the SN should:

- Discuss with the Medical Practitioner whether expert input is needed.
- Document all information in the appropriate **visible sections of DonorPath**, attaching reports where needed.
- Communicate the finding and any additional required information to centres assessing organ offers.

4.2. SHARING CLINICAL INFORMATION

4.2.1. In circumstances where new clinical information is identified post consent/authorisation but pre-registration it is the responsibility of the SN to clearly document any findings on the visible sections of DonorPath considering any implications for recipients as per **POL188**.

4.2.2. In circumstances where the donor is already registered with Hub Operations and offering has commenced, it is the responsibility of the SN to ascertain from the OAS whether offering has commenced and whether any organs have been accepted for transplantation and/or which organs remain on offer.

4.2.3. In circumstances where the new clinical finding requires further clinical explanation it is the responsibility of the SN to contact all receiving centres and voice record any discussions utilising **SOP6651 OTDT Manual 11**. All communication with Hub Operations and Receiving Centres regarding non-acceptance of organs must be clearly documented in DonorPath

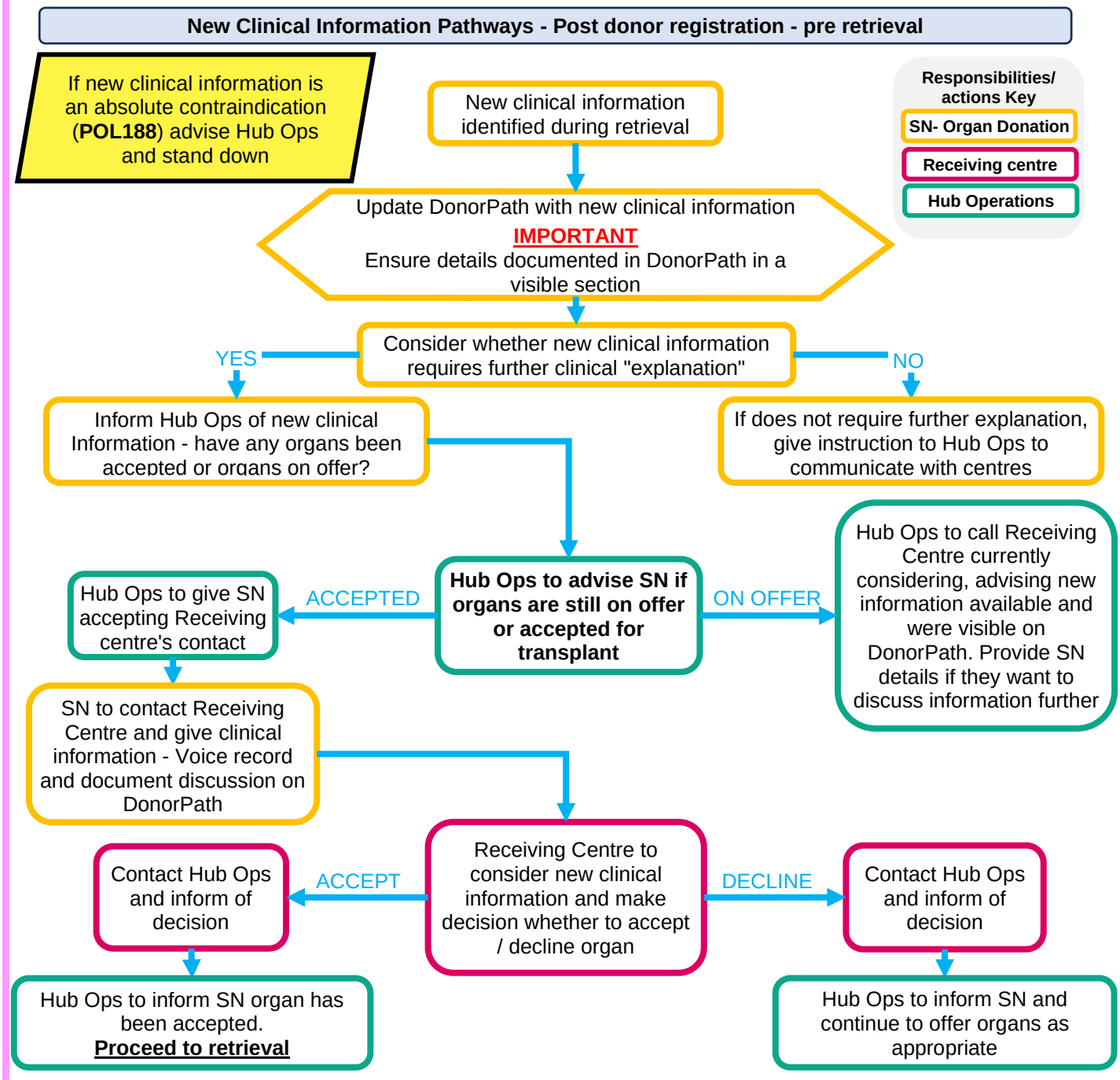
4.2.4. In circumstances where the new clinical finding does not require further clinical explanation the OAS should on request of the SN, pass on to receiving centres that new information is available to view on TransplantPath, noting all communication in the relevant donor's notes in NTxD.

ADVICE

Any new information post registration but pre-retrieval should go in main body of CDD relevant section and not in the specific 'Organ Retrieval / New significant clinical information' box, within the 'Retrieval Information' section of DonorPath.

Any summary of significant outstanding results from characterisation will need documenting in main body of CDD relevant section.

Please see below:



End of Section Procedure

5. NEW CLINICAL INFORMATION IDENTIFIED DURING RETRIEVAL

Section Contents - Hyperlinked

	Manual Index
5.1	Findings Requiring Additional Action
5.2	Sharing Clinical Information
	Section Procedural Diagram
	Associated Documents and References (A-Z)

5.1. FINDINGS REQUIRING ADDITIONAL ACTION

If a finding requiring additional action is identified during retrieval, the SN and Hub Operations must use critical thinking to assess its significance and implications for donation safety and quality, considering:

- the nature of the finding,
- the point reached in the retrieval process,
- organs already accepted or on offer, and
- time-sensitive cardiothoracic and liver considerations.

5.1.1. If histopathology or other tests (blood / specimen) are required, the Lead Surgeon must inform the SN and follow Findings During Retrieval Requiring Histopathology or Microbiology Assessment. The SN must facilitate the testing and complete **FRM5867**. Communication must be timely to Receiving Centres, and the SN should attach relevant reports/images in DonorPath to make them visible in TransplantPath.

5.1.2. The SN should only stand down the donation process if they jointly confirm with the Lead Surgeon that absolute contraindications exist affecting all organs/tissue according to **POL188**. If necessary, the SN should escalate concerns regarding the finding/s to ODLT On-Call for management support. If the donor process stands down, the SN must follow the relevant procedure for communication with the family, working with hospital staff and inform Coroner / Procurator Fiscal of events if applicable.

5.1.3. If a new finding **does not** meet **POL188** absolute contraindication criteria, the SN should:

- Discuss with the Lead Surgeon whether expert input is needed.
- Document all information in the appropriate **visible sections of DonorPath**, attaching reports where needed.
- Communicate the finding and any additional required information to centres assessing organ offers.

5.1.4. In the exceptionally unlikely event that pregnancy identified, **retrieval must stop immediately and urgent advice sought** from ODLT On-Call, as per **SOP5499 OTDT Manual 4**.

5.2. SHARING CLINICAL INFORMATION

In circumstances where new clinical information is identified during retrieval, consideration needs to be given by the SN to the nature of the new clinical information and the potential impact for receiving centres.

Please note: There may be times where one centre has accepted an organ, but the transplant is being facilitated at another centre. Information will need to be shared with both the registering centre and the transplanting centre at this point in the donation process. In these circumstances it is the responsibility of the OAS to advise the SN of these unique circumstances, and the responsibility of the SN to ensure ALL new clinical information is shared.

5.2.1. On all occasions where histopathology is required, please follow Findings During Retrieval Requiring Histopathology or Microbiology Assessment. The order and priority of communication cascade will need to be determined by the SN in relation to the potential implications for the identified recipients determined by nature of new finding and which organs/tissues are being retrieved.

5.2.2. It is imperative that the SN must update DonorPath with new clinical information utilising the visible sections of DonorPath (known as the Core Donor Data). **N.B.** Information entered in sections without this symbol CANNOT be seen by Recipient Centres.

5.2.3. 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. The SN should ensure the Lead Surgeon documents in the patient's medical record the details of the finding/s, any implication (if known) for the safety and quality of the organ and potential implications for the recipient.

5.2.4. **IMPORTANT:** SNs must continue to notify all receiving centres of any significant new information, including histopathology. The SN must inform Hub Operations of the update and where it is located in DonorPath/TransplantPath and obtain receiving-centre details to complete a verbal update. If time-critical, the SN should request a '**CRITICAL INFO ALERT**' from Hub Operations. A dated and timed update must also be added to the CDD in visible section of DonorPath

ADVICE
Any summary of significant outstanding results from characterisation will need documenting in main body of CDD relevant section.
New information post offering / pre retrieval / during retrieval should go in main body of CDD relevant section.

5.2.5. When an organ is declined based on new clinical information discovered during retrieval, the SN can request the OAS to continue offering any declined organs and/or contact all accepting receiving centres to immediately notify of the new relevant clinical information and where that information is located in TransplantPath. It is the responsibility of the SN to ensure that this information is shared with all receiving centres by clearly documenting and communicating with the OAS.
N.B. A clinical conversation may still be required by the SN, but the initial message can, where required, be sent via Hub Operations to alert receiving centres that new information has been identified and that the SN will make contact as soon as possible.
An example may be:

Donor XXXXXX

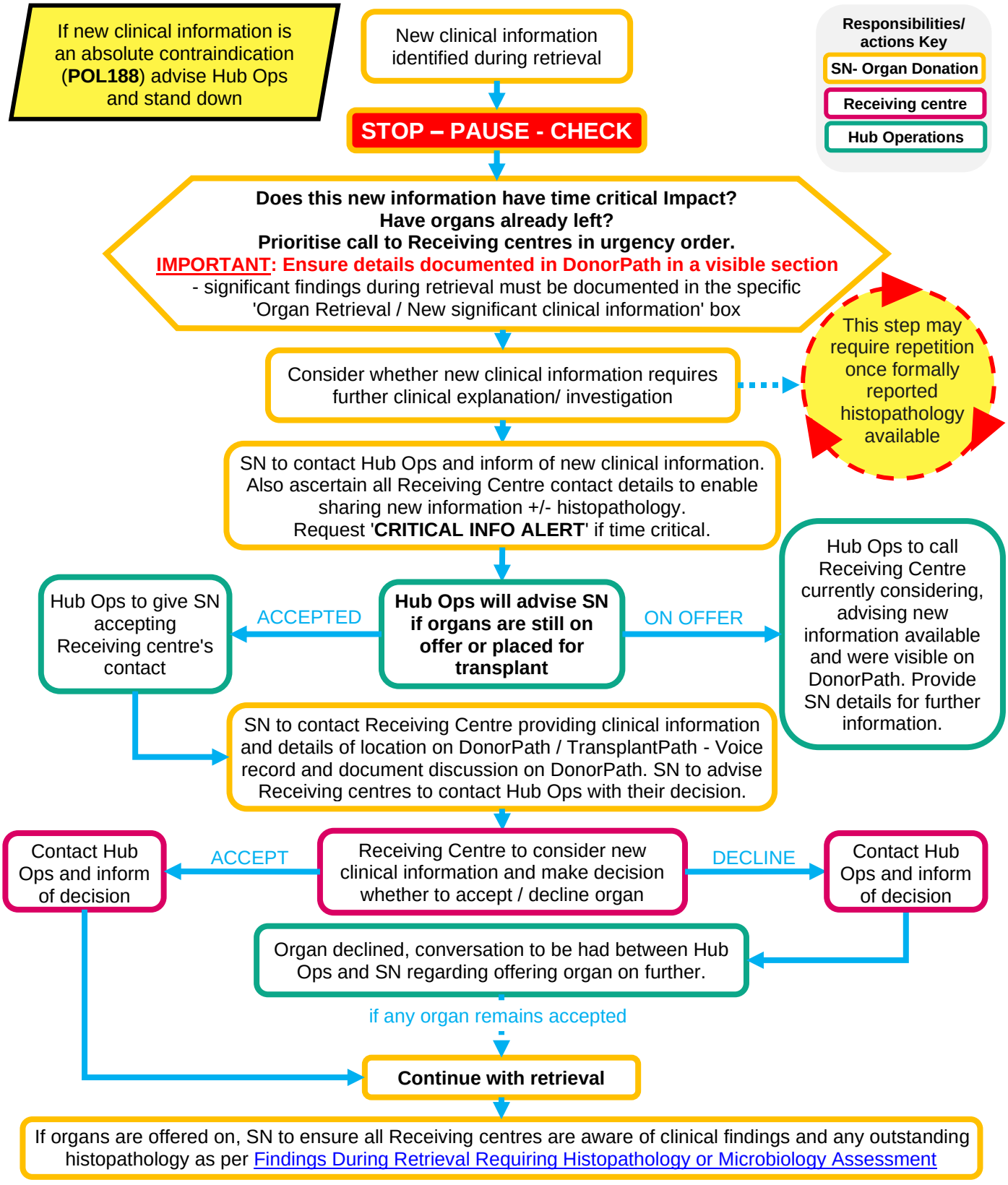
Urgent – Lesion requiring biopsy identified during retrieval. Clinical update will be provided shortly by SN. Currently sourcing histopathology.

5.2.6. In circumstances where the new clinical finding requires further clinical explanation it is the responsibility of the SN to contact all centres and voice record any discussions utilising **SOP6651 OTDT Manual 11.** Any such discussions between the SN and receiving centre MUST be clearly documented within DonorPath Sequence of Events.

5.2.7. In circumstances where the new clinical finding does not require further clinical explanation the OAS should, on request of the SN, pass on to receiving centres that new information is available on TransplantPath, noting all communication on the relevant donor's notes in NTxD.

Please see below:

New Clinical Information Pathways - During retrieval



End of Section Procedure

6. NEW CLINICAL INFORMATION POST RETRIEVAL BUT PRE-TRANSPLANTATION

Section Contents - Hyperlinked

	Manual Index
6.1	Findings Requiring Additional Action
6.2	Sharing Clinical Information
	Section Procedural Diagram
	Associated Documents and References (A-Z)

6.1. FINDINGS REQUIRING ADDITIONAL ACTION

6.1.1. Where a new finding is identified at a transplant centre, rapid communication is essential. When a transplant centre identifies a new clinical finding post-retrieval and pre-transplantation, the centre must follow New Findings Made at Transplant Centres Requiring Histopathology Assessment. The SN must ensure all other receiving centres are informed and participate in a clinical discussion, minimising risk to patients awaiting imminent transplantation.

6.1.2. The SN must document all findings in DonorPath, including any outstanding results (e.g., frozen section, biopsy, histopathology, confirmatory specimens) and expected timescales. Concerns relating to the findings should be escalated as needed to ODLT On-Call. Communication must be timely to Receiving Centres and the SN should attach relevant reports/images in DonorPath to make them visible in TransplantPath.

6.1.3. The SN must follow the relevant procedure for communication with the family, working with hospital staff and inform Coroner / Procurator Fiscal of events if applicable.

6.2. SHARING CLINICAL INFORMATION

6.2.1. It is the responsibility of the Receiving Centre, prior to implantation of the received organ, to contact Hub Operations. The OAS will put them in direct contact with the SN team to ensure clear clinical oversight by the SN. In all circumstances, it is the responsibility of the SN to discuss any new clinical information with the receiving centre and for the SN to formulate a clear plan for cascade of the information ensuring clear agreed timelines for receiving and sharing information, as per New Findings Made at Transplant Centres Requiring Histopathology Assessment

6.2.2. Any significant findings or new clinical information identified post retrieval but pre-transplantation that require further explanation must be documented in the specific 'Organ Retrieval / New significant clinical information' box, within the ‘Retrieval Information’ section of DonorPath.

N.B. Sometimes an organ is accepted by one centre but transplanted at another. In these cases, information must be shared only with the registering centre, as they are responsible for the recipient’s care and follow-up. The OAS must notify the SN of this arrangement, and the SN must ensure ALL new clinical information is shared appropriately.

6.2.3. **IMPORTANT:** SNs must continue to notify all receiving centres of any significant new information, including histopathology. The SN must inform Hub Operations of the update and where it is located in DonorPath/TransplantPath and obtain receiving-centre details to complete a verbal update. If time-critical, the SN should request a ‘**CRITICAL INFO ALERT**’ from Hub Operations. A dated and timed update must also be added to the CDD in any visible section of DonorPath.

6.2.4. The SN must prioritise contact with centres based on clinical knowledge and cold ischaemic times.

6.2.5. All conversations between the SN and the receiving centre must be voice recorded as per **SOP6651 OTDT Manual 11**. Information and decisions must be clearly documented within the Sequence of Events section on DonorPath.

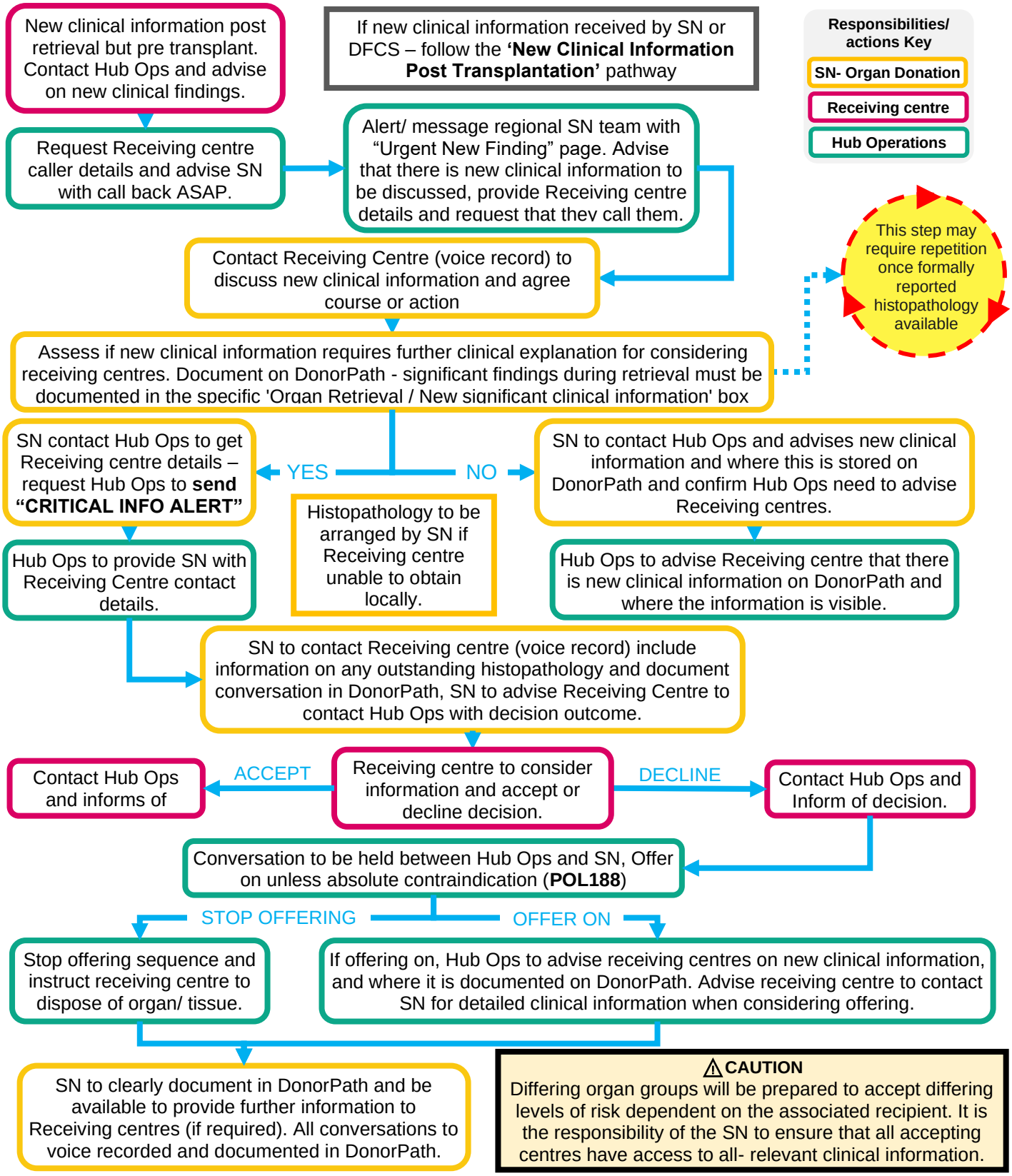
ⓘ ADVICE

Files, images and videos (organ media) uploaded in DonorPath are visible in TransplantPath when marked with the Wi-Fi symbol.
TransplantPath users can also upload files and organ media to support organ/tissue assessment at the Receiving Centre. However, only uploaded files will be visible on DonorPath and TissuePath; organ media will not transfer back to DonorPath and remain visible only to TransplantPath users.

TransplantPath users are responsible for informing Hub Operations and/or the SN whenever new information is added to the digital donor record to coordinate sharing clinical information.

Please see below:

New Clinical Information Pathways – Post Retrieval - Pre Transplantation



End of Section Procedure

7. NEW CLINICAL INFORMATION POST TRANSPLANTATION

Section Contents - Hyperlinked

	Manual Index
7.1	Findings Requiring Additional Action
7.2	Sharing Clinical Information
	Section Procedural Diagram
	Associated Documents and References (A-Z)

7.1. FINDINGS REQUIRING ADDITIONAL ACTION

7.1.1. Where a new finding is identified post transplantation, the SN must share the clinical information with all relevant receiving centres. Hub Operations provides support in facilitating communication under the clinical direction of the SN, to ensure all information is accessed and communicated.

7.1.2. The SN must document all findings in DonorPath, including any outstanding results (e.g., frozen sections, biopsies, histopathology, confirmatory specimens) and expected timescales. Any concerns should be escalated to ODLT On-Call as required. Communication with Receiving Centres must be timely, and relevant reports/images should be attached in DonorPath to be visible in TransplantPath.

7.1.3. The SN must follow the relevant procedure for communication with the family, working with hospital staff and inform Coroner / Procurator Fiscal of events if applicable.

7.2. SHARING CLINICAL INFORMATION

7.2.1. All Regional ODST must have systems to follow up any and all outstanding results and escalate any unexpected new findings. Any new information about a deceased organ donor that emerges post-implantation must be shared with all receiving centres immediately.

7.2.2. Any unexpected significant findings or clinical information identified post transplantation that require further explanation must be documented in the specific 'Organ Retrieval / New significant clinical information' box, within the 'Retrieval Information' section of DonorPath.

7.2.3. **IMPORTANT:** SNs must continue to notify all receiving centres of any significant new information, including histopathology. The SN must inform Hub Operations of the update and where it is located in DonorPath/TransplantPath and obtain receiving-centre details to complete a verbal update. If time-critical, the SN should request a '**CRITICAL INFO ALERT**' from Hub Operations. A dated and timed update must also be added to the CDD in any visible section of DonorPath.

7.2.4. New clinical information post implantation can include but is not exclusive to:

- Outstanding results as per handover **FRM5499**.
- Outstanding final microbiology blood results (follow **SOP6514 OTDT Manual 3**).
- Clinical information about a transplant recipient that may affect other transplanted organs/tissues.
- Outstanding histopathology results.
- Outstanding information following completion of GP assessment post transplantation.

7.2.5. It is the responsibility of the Regional SN team to follow-up all outstanding results and update relevant sections of CDD. Deceased donation outstanding results include but are not exclusive to:

- Blood cultures taken at the donor hospital and outstanding at the time of donation
- Sputum samples taken at the donor hospital and outstanding at the time of donation

7.2.6. It is the SNs responsibility to ensure new clinical information is shared appropriately and to update the relevant sections of DonorPath.

7.2.7. If an Organ and Tissue Donor Outcome Summary is available, it can be used to identify receiving centres. If not, the SN must request Hub Operations OAS to provide the details from NTxD.

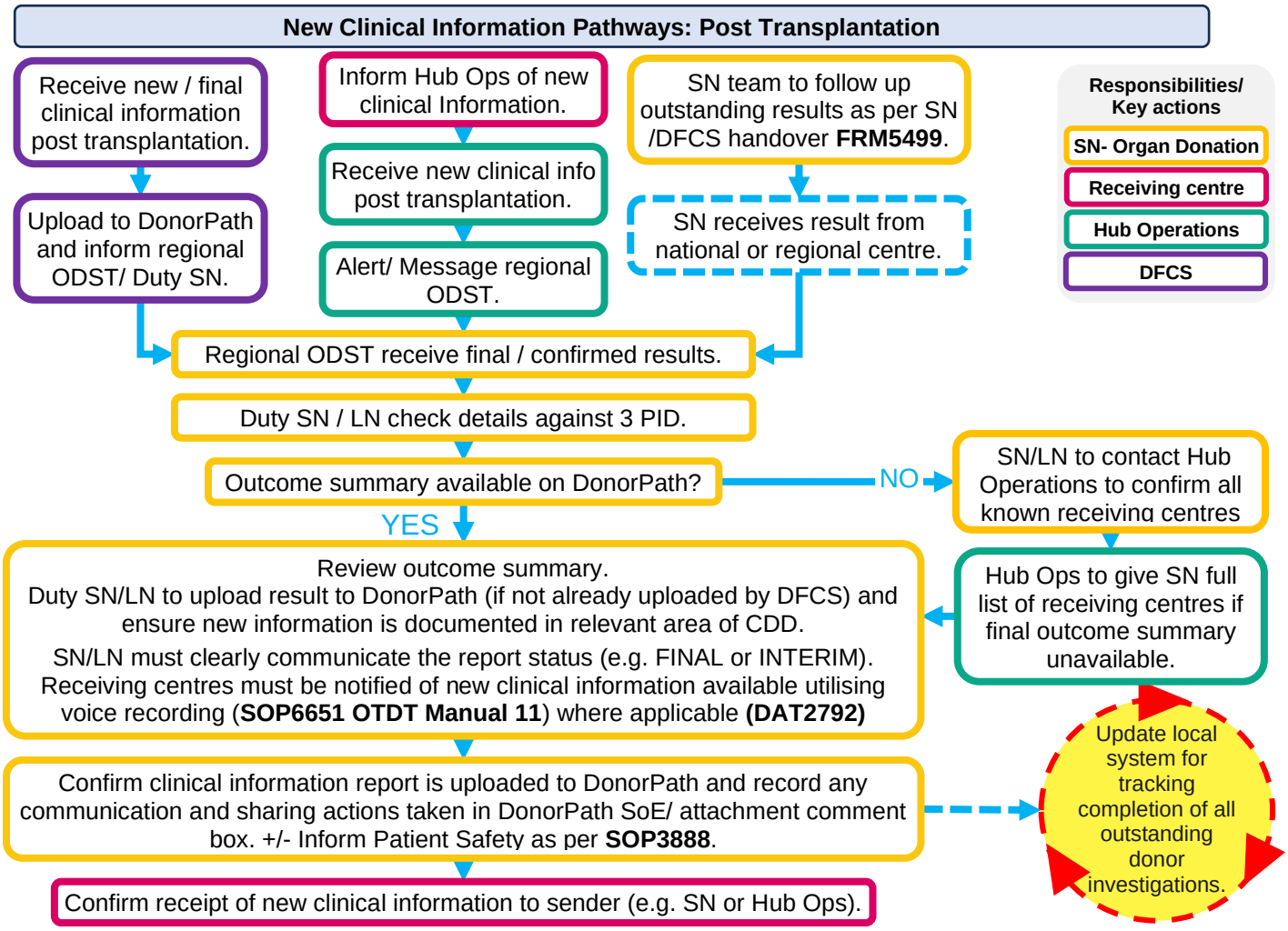
7.2.8. **Please note:** Sometimes an organ is accepted by one centre but transplanted at another. In these cases, information must be shared only with the registering centre, as they are responsible for the recipient's care and follow-up. The OAS must notify the SN of this arrangement, and the SN must ensure ALL new clinical information is shared appropriately.

7.2.9. **RECEIVING CENTRE REQUESTS FOR BLOOD / TISSUE SAMPLES**
In any case where a receiving centre requests access to, or additional testing of, blood or tissue samples held by NHSBT or the donor hospital, the SN must escalate the request to the regional LN for onward escalation to the Patient Safety Team.

ⓘ ADVICE

Files, images, and videos (organ media) uploaded to DonorPath are visible in TransplantPath when marked with the Wi-Fi symbol.
TransplantPath users can also upload files and organ media to support organ and tissue assessment; however, only uploaded files transfer back to DonorPath and TissuePath. Organ media uploaded in TransplantPath remains visible only within TransplantPath.
TransplantPath users are responsible for informing Hub Operations and/or the SN whenever new information is added to the digital donor record to support timely sharing of clinical information.

See below:



End of Section Procedure

8. FINDINGS DURING RETRIEVAL REQUIRING HISTOPATHOLOGY OR MICROBIOLOGY ASSESSMENT

Section Contents - Hyperlinked

	Manual Index
8.1	HISTOPATHOLOGY - If a lesion is identified during retrieval
	Procedural diagram when LESION found during retrieval
8.2	MICROBIOLOGY - If any microbiology findings are identified during retrieval
	Procedural diagram when sample requiring MICROBIOLOGY testing found during retrieval
	Associated Documents and References (A-Z)

During organ retrieval, suspicious lesions or findings may require histopathology or microbiology assessment (services not commissioned by NHSBT and with variable sample destinations) and this section sets out guidance for all involved personnel (including SNs, NORS teams, Histopathologists, Microbiologists, Biomedical Scientists, Hub Operations staff, and Receiving Centres) to safeguard organ safety.

ⓘ ADVICE

Three points of identification MUST always be present to ensure the correct identification of the donor as per Patient Identifiable Data (MPD1086).
In some circumstances, a laboratory report may not have the appropriate identifier available in the allocated demographics area. In this case, the PID must be documented in the comment box of the report.

8.1. HISTOPATHOLOGY - If a lesion is identified during retrieval

8.1.1. On all occasions access to histopathology should be considered in the following order:

1. Donor Hospital (Trust / Board)
2. Attending NORS Team base hospital
3. 'Recipient Centre' (sample sent with accepted organ for histopathology) in order of urgency
    a) Cardiothoracic
    b) Liver
    c) Kidney

⚠ CAUTION

If a whole organ is sent for histopathology, it must travel with an organ for transplantation to a transplant centre or with the NORS team to maintain traceability and be recorded on the appropriate HTA-A Form. The receiving centre is not required to complete an HTA-B Form.

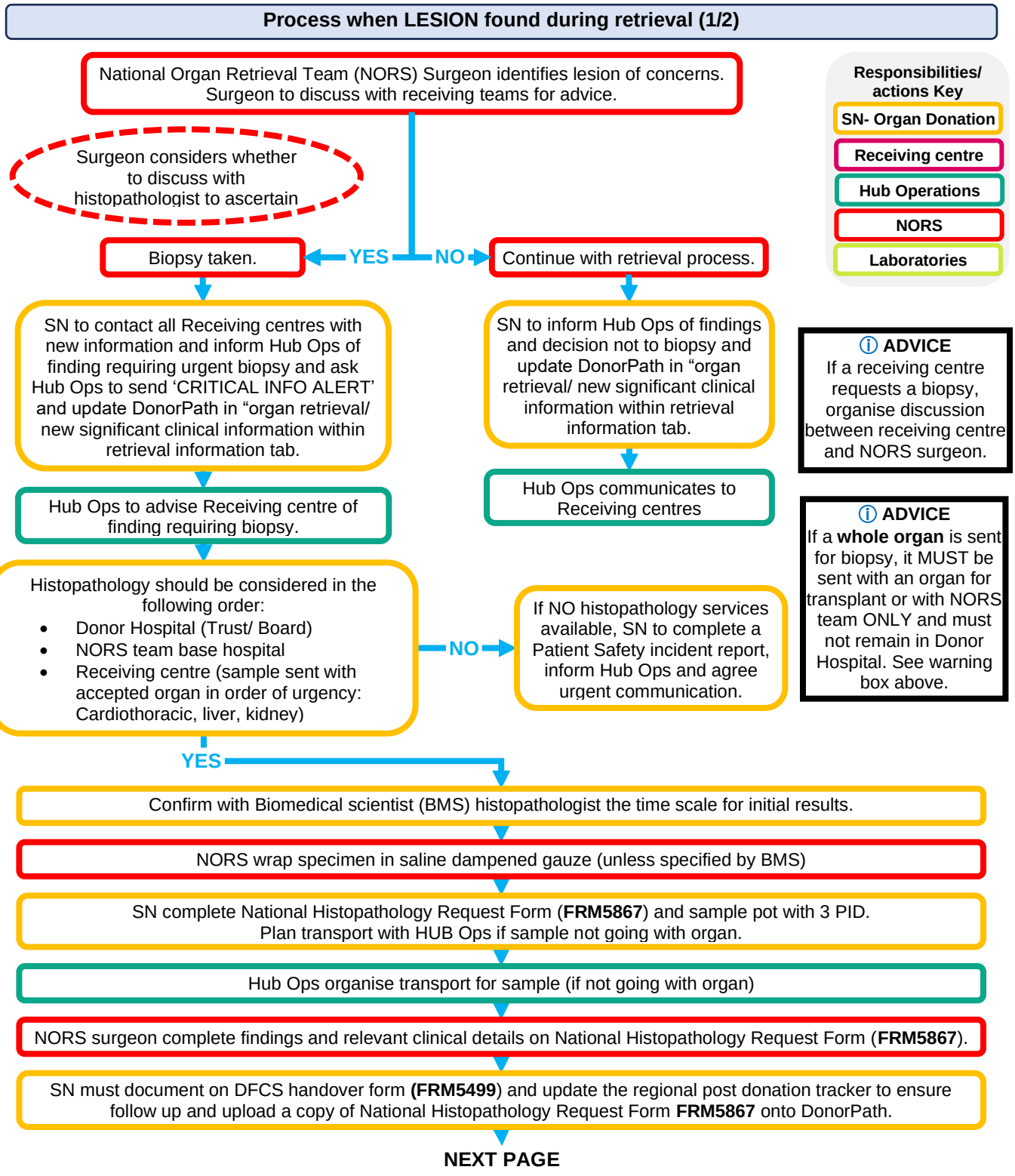
8.1.2. Care must be taken to explore all options, while considering the donor type (DBD/DCD) and the stage of the retrieval process when the finding is made. Receiving centres must be informed immediately of any suspicious lesion, especially as cardiothoracic surgery may already have begun. For example:

- **DBD** – whether prior to or after cross clamp. It is permitted to delay cross clamp for 60 minutes to identify a centre/pathologist who will provide an opinion.
- **DCD** – will always be post asystole therefore impact on cold ischaemic times. If novel therapies are in use such as NRP / Organ Ox, this may allow additional time to seek histopathology support. (NRP applies only to abdominal organs, and OrganOx applies only to liver).

8.1.3. On all occasions immediate findings must be communicated to all centres as per the principles of Sharing Clinical Information.

8.1.4. **IMPORTANT**: In circumstances where no histopathology is available resulting in stand-down of the deceased organ donors a Patient Safety notification should be made.

8.1.5. The procedural diagram below outlines the steps to be taken when histopathology resource is identified. On all occasions where samples are taken for histopathology **FRM5867** must be used which is available via the SN Donor Pack.



Process when LESION found during retrieval (2/2)

SN informs Hub Ops of where histopathology will be completed and expected timescales for initial results confirming communication cascade.

Samples are processed on arrival by BMS/ Histopathology

ⓘ ADVICE
If suspicious lesion is noted at the Receiving centre that was not noted during retrieval and a biopsy is taken, Hub Ops must be immediately contacted to ensure all other centres are informed of findings.

ⓘ ADVICE
If at any point a decision is made by anyone involved NOT to process a sample or timescales are altered, then ALL receiving centres MUST be informed to ensure the decision does not impact on the implantation of any organs. This is still the case if it is felt the lesion is not suspicious.

Responsibilities/ actions Key
- SN- Organ Donation
- Receiving centre
- Hub Operations
- NORS
- Laboratories

INTERIM REPORT

When initial results are available contact the SN who can provide details of implanting surgeons/ recipient coordinators if needed to discuss difficult/ equivocal case. Provide SN with preliminary findings and confirm written report/ summary will be sent to Hub Ops via secure email immediately to enable dissemination to Receiving centres.

Email a copy/ summary of the frozen section report immediately to odthub.operations@nhsbt.nhs.uk (via secure email). Include pathologist name and contact number in case surgeon needs to discuss case.
Report must include 3 PID as per **MPD1086**

Hub Ops must disseminate to the SN (regional inbox).

SN to review report and check if further clinical explanation required. Upload to DonorPath and under Histopathology Interim, title Frozen section.
SN must update CDD 'Organ Retrieval / New significant clinical information' box, within the 'Retrieval Information' section of DonorPath with the new clinical information.

Hub Ops to disseminate to Receiving centre when requested by SN.

SN to liaise with histopathologist if results not received within expected timescales.

FINAL REPORT

Histopathology to email report to odthub.operations@nhsbt.nhs.uk (via secure email). Report must include 3 PID as per **MPD1086**

Hub Ops to the forward final report via secure email to SN (regional inbox)

SN to update tracker and upload final report under Histopathology Final. SN must update CDD 'Organ Retrieval / New significant clinical information' box, within the 'Retrieval Information' section of DonorPath with the new clinical information.

SN to contact Receiving centre to advise new information available on TransplantPath

⚠ CAUTION
A final report is required to ALL biopsy samples even if frozen section is benign. If final report not received within expected timescales. SN MUST contact histopathologist to discussed expected time to receipt of report.

End of HISTOPATHOLOGY Procedure

8.2. MICROBIOLOGY - If any microbiology findings are identified during retrieval

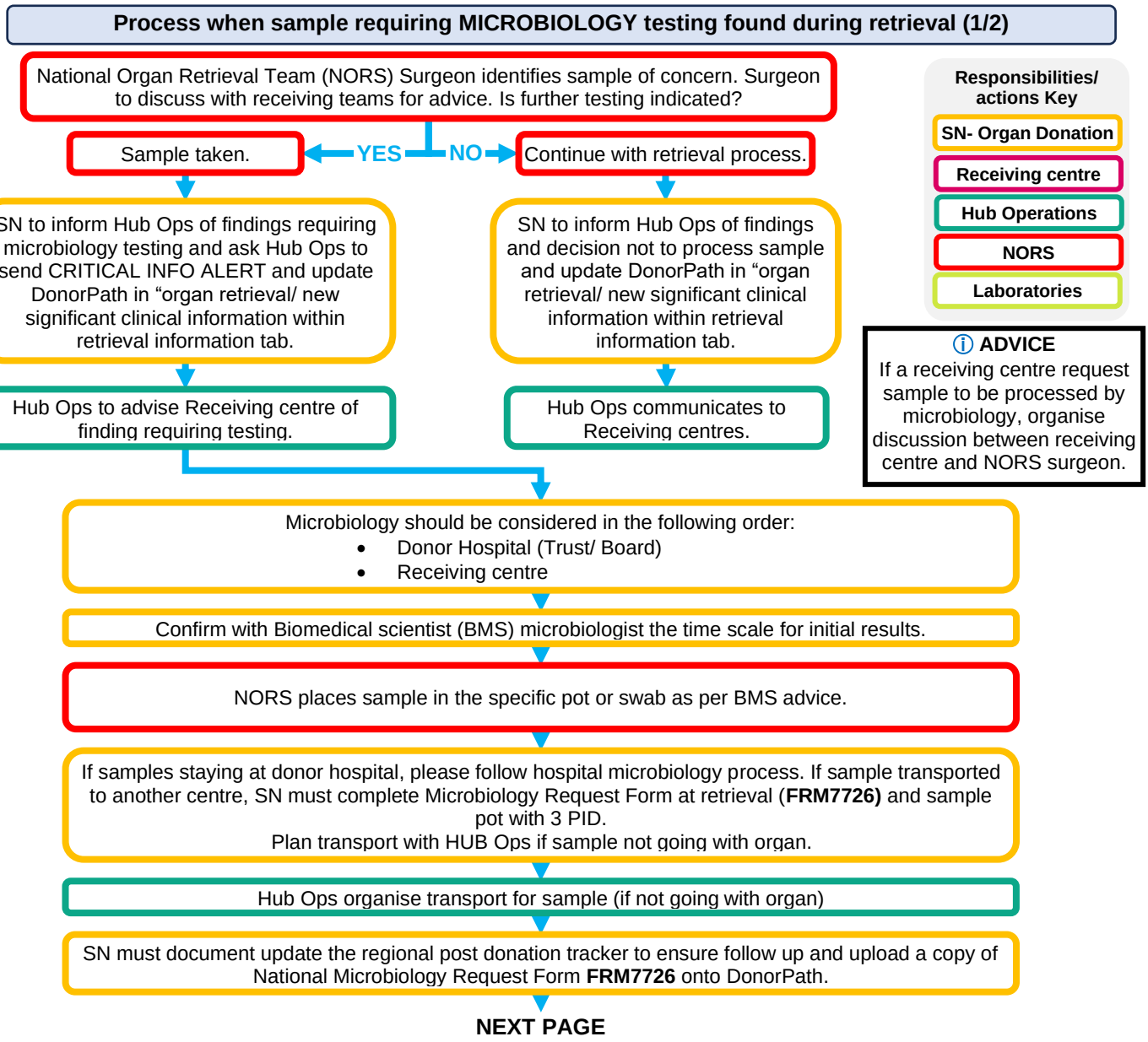
8.2.1. On all occasions access to microbiology should be considered in the following order:

1. Donor Hospital (Trust / Board)
2. Receiving Centre' (sample sent with accepted organ for microbiology)

8.2.2. Immediate findings must be communicated to all centres as per principles of Sharing Clinical Information.

8.2.3. **IMPORTANT**: In circumstances where no microbiology is available resulting in stand-down of the deceased organ donors a Patient Safety notification should be made.

8.2.4. The process below outlines the steps to be taken when microbiology resource is identified. On all occasions where samples are taken for microbiology **FRM7726** must be used which is available via the SN Donor Pack.



Process when sample requiring MICROBIOLOGY testing found during retrieval (2/2)

Responsibilities/ actions Key
- SN- Organ Donation
- Receiving centre
- Hub Operations
- NORS
- Laboratories

SN informs Hub Ops of where microbiology will be completed and expected timescales for results confirming communication cascade.

Samples are processed on arrival by BMS/ Microbiology

ⓘ ADVICE
If a new finding is noted at the Receiving centre that was not noted during retrieval and a sample is taken, Hub Ops must be immediately contacted to ensure all other centres are informed of findings.

ⓘ ADVICE
If at any point a decision is made by anyone involved NOT to process a sample or timescales are altered, then ALL receiving centres MUST be informed to ensure the decision does not impact on the implantation of any organs. This is still the case if it is felt the finding is not suspicious.

SN to obtain microbiology results, update tracker and upload report under Microbiology Final, title: *name of sample*. SN must update CDD 'Organ Retrieval / New significant clinical information' box, within the 'Retrieval Information' section of DonorPath with the new clinical information.

SN to contact Receiving centre to advise new information available on TransplantPath.

Further Clinical Explanation Required?

If further clinical discussion is required, SN to contact Receiving centres.

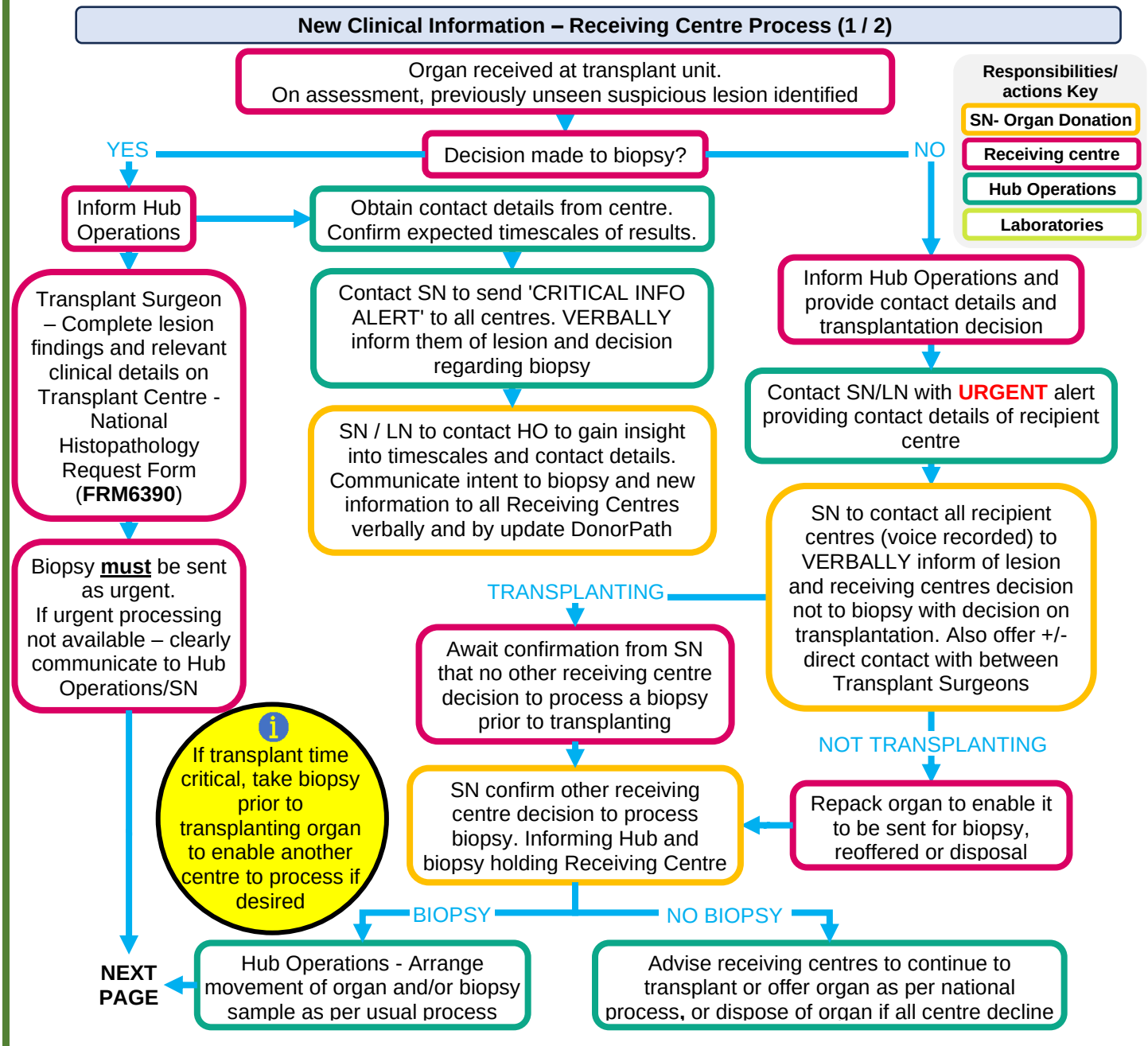
End of MICROBIOLOGY Procedure

9. NEW FINDINGS MADE AT TRANSPLANT CENTRES REQUIRING HISTOPATHOLOGY ASSESSMENT

Section Contents - Hyperlinked

	Manual Index
9	Procedural diagram - New Clinical Information – Receiving Centre Process
	Associated Documents and References (A-Z)

Upon arrival at a Transplant Centre, physical assessment may reveal suspicious lesions requiring histopathological examination. As NHSBT does not provide or commission histopathology services, the destination and handling of these samples may vary. This section outlines the processes and responsibilities for all parties involved in histopathological assessment that may affect organ safety, including Transplant Centres, Histopathologists, Biomedical Scientists, Hub Operations staff, and SNs.



New Clinical Information – Receiving Centre Process (2 / 2)

Responsibilities/ actions Key

- SN- Organ Donation
- Receiving centre
- Hub Operations
- Laboratories

Whilst the results may be directly communicated to a local recipient coordinator/surgeon they **MUST** also be sent to ODT Hub directly to enable other centres to be informed.

Histopathology / Receiving Centre - sample arrives at centre and processed

Histopathology - When results are available contact the implanting surgeon/recipient coordinator to discuss/inform.

Contact Hub Operations with initial verbal interim report.

Be available for SN to call back for **verbal report**. (In case of time critical decision making for other organ groups) Provide interim findings and send report/summary via secure email to Hub Operations immediately to enable dissemination to relevant centres.

Hub Operations – share verbal interim report with SN/LN to agree dissemination.

SN/LN - If time critical for other organ groups - contact histopathologist (voice recorded) for verbal findings, pending formal report. SN must action these results.

DELAYED RESULTS
SN/LN– Confirm with HO results not received if not seen within expected timescales. If they have not been sent to HO, SN to follow up immediately.

Histopathology - Email a copy/summary of the frozen section report immediately to: odthub.operations@nhsbt.nhs.uk via secure email and Hub Operations will disseminate regional SN team for review. Include pathologists name and contact number in case surgeon needs to discuss case. Email must include 3 donor PID provided on request form (Name, DOB and NHS/CHI Number). If histopathology performed under recipient PID, Donor PID must be included on the report in comments section.

Hub Operations – Liaise with SN/LN to review. If no further clinical explanation required, LN/SN to agree dissemination to all receiving centres / NRC / SNBTS via secure email. Contact all receiving centres urgently via phone to ensure receipt.

Histopathology - Email **final report** to odthub.operations@nhsbt.nhs.uk via secure email and Hub Operations will disseminate regional SN team for review.

Hub Operations – Liaise with SN/LN to review. If no further clinical explanation required, LN/SN to agree dissemination to all receiving centres / NRC / SNBTS via secure email. Contact all receiving centres urgently via phone to ensure receipt.

SN/LN – Ensure all Receiving Centre receipt of final results of any histopathology sent at time of retrieval, as per Findings During Retrieval Requiring Histopathology or Microbiology Assessment. Final results are required even if provisional results indicate a benign result.

End of Section Procedure

10. COMMUNICATING ADDITIONAL FINDINGS AND ACTIONS WITH DONOR FAMILIES

Section Contents - Hyperlinked

	Manual Index
10.1	Communicating Findings Requiring Additional Action to a Family Pre Donation
10.2	Communicating to a Family Any Findings Requiring Additional Action That Have Been Identified During the Organ Retrieval Operation
10.3	Communicating to a Family Any Post Donation Findings Requiring Additional Action
	Associated Documents and References (A-Z)

There may be instances where additional findings are discovered that can have an impact upon the organ donation process which needs to be communicated to the patient's family. In accordance with **SOP5049 OTDT Manual 8**, the SN should ensure that they work closely with donor hospital staff to ensure that patient families are provided with the appropriate support and care throughout their experience at the hospital and beyond.

As part of providing this support and care to patient's families, during the consent/authorisation conversation with the patient's family the SN should identify the appropriate person to contact, if required, during or following the donation process.

The SN should also confirm the family's decisions to stay, or leave, the hospital during the donation process, so that the SN is aware of the most efficient way to contact the appointed individual, if required.

There may be times when a family has requested not to receive further communication from the SN. However, the SN must inform the family that if an additional clinical finding is identified that could affect the health of a family member, now or in the future, then it is their responsibility to contact the family to inform them of this.

If pregnancy is suspected either following consent or during the organ retrieval process, please refer to **SOP6405 OTDT Manual 1** and **SOP5499 OTDT Manual 4** regarding Pregnancy in Donation for detailed guidance on how to proceed, in addition to using this manual as a framework for communication.

10.1. COMMUNICATING FINDINGS REQUIRING ADDITIONAL ACTION TO A FAMILY PRE DONATION

10.1.1. If organ and/or tissue donation cannot proceed because an absolute contraindication has been identified OR if all transplant centres have declined organs and/or tissues for transplantation because of a clinical finding, the SN should utilise the relevant section of New Clinical Information Post Consent / Authorisation and Pre Donor Registration to guide their practice.

10.1.2. A conversation should be held with the medical practitioner and other relevant HCPs to determine a plan of action and identify any family members that may be implicated by the clinical finding. The areas for discussion should include, but are not limited to:

a) Is confirmatory testing of the clinical finding required before speaking to the family?
b) Who should lead the conversation with the patient's family?
c) What support services are available to the family if required?
d) What detail of information should be given? What is appropriate?
e) Should other relevant healthcare professionals (for example, specialist medical practitioners for infectious diseases) be present during the conversation?
f) What should be the agreed course of action to take following the conversation (for example, referral to specialist/community medical practitioners for further testing)?

10.1.3. The SN should document in DonorPath the agreed plan of action when communicating with patient's family.

10.1.4. The SN may be informed by the medical practitioner of a clinical presentation that is classed as legally notifiable. The SN should utilise Statutory Notifiable Diseases to guide their practice. Expert advice from a specialist medical practitioner in public health / Infectious diseases should be sought to advise on the potential risks of transmission.

ⓘ ADVICE

- **The SN must work with the hospital team when planning a conversation with the patient's family.**
- **This conversation should only take place after agreement has been reached covering areas for discussion.**
- **The medical practitioner should lead this conversation with the patient's family, with the SN providing information relating to organ donation and additional support where required. Additional support and advice should be sought from specialist medical practitioners where required.**
- **There may be circumstances when communication with the family occurs prior to confirmatory results being available and a plan being made with the medical practitioner. In such cases information should be limited to known facts and information available at that time.**

10.1.5. Before undertaking the conversation with the family, in conjunction with the medical practitioner, the SN should consider if the timing of the conversation is appropriate. If required, the SN should seek advice from the ODST LN / geographical RhoN / ODLT On-Call.

10.1.6. If the family is present and it is agreed that it is appropriate to do so, the SN should facilitate the meeting with the local hospital staff and/or specialist practitioner(s), ensuring privacy of the environment, and that the relevant family members are present.

10.1.7. If the family is not present the SN should telephone the agreed appropriate person to advise that donation is/was unable to proceed, and:

give additional information as requested by the family;
AND/OR
request that the family either returns to the hospital or arrange a date and time for them to attend an appointment, so that medical and/or specialist practitioners are available to speak with them in further detail. The SN must make all attempts to ensure that they are present at this meeting, so they are able to answer all questions related to organ and/or tissue donation.

ⓘ ADVICE

The SN must utilise SOP6651 OTDT Manual 11 regarding voice recording of conversations when disclosing clinical information to family members, ensuring that consent is given for the conversation to be recorded.

10.1.8. The Confidentiality: NHS Code of Practice (DoH, 2003) confirms there are exceptional circumstances where confidentiality can be breached:

"There are exceptions to the duty of confidence that may make the use or disclosure of confidential information appropriate. Statute law requires or permits the disclosure of

confidential information in certain circumstances. Case law has also established that confidentiality can be breached where there is an overriding public interest"

"Under common law, staff are permitted to disclose personal information in order to prevent and support detection, investigation and punishment of serious crime and/or to prevent abuse or serious harm to others where they judge, on a case-by-case basis, that the public good that would be achieved by the disclosure outweighs both the obligation of confidentiality to the individual patient concerned and the broader public interest in the provision of a confidential service".

10.1.9. As agreed with the local hospital team, either via telephone or at the arranged meeting, the family should be fully informed of the reason why organ and/or tissue donation could not proceed. The SN should consider the action plan agreed with the local hospital staff when speaking with the family. Any questions should be answered in full and appropriate advice and support should be given to the patient's family as required.

10.1.10. The patient's family should also be given the appropriate contact details of specialist medical practitioners in public health/infectious diseases to provide additional guidance and expert advice, if required and appropriate.

10.1.11. The SN must record details of all conversations with the patient's family medical practitioner(s) and specialist practitioner(s) should. This must also be documented in DonorPath in sequence of events and, where possible, in the medical records.

10.1.12. The SN must also document clearly in the SoE on DonorPath/PDA, giving clear details as to the reasons why donation could not proceed.

10.2. COMMUNICATING TO A FAMILY ANY FINDINGS REQUIRING ADDITIONAL ACTION THAT HAVE BEEN IDENTIFIED DURING THE ORGAN RETRIEVAL OPERATION

10.2.1. The SN should utilise New Clinical Information Identified During Retrieval section for guidance and direction on the actions to take if a finding requiring additional action is identified during the organ retrieval process.

10.2.2. If a specific organ has been declined due to a clinical finding yet other organs are retrieved for the purposes of transplantation, the SN should communicate the full outcome of the donation through the normal communication pathway agreed with the patient's family. This will have been agreed with the patient's family as part of the consent/authorisation process.

10.2.3. If all organs and/or tissues have been found to be unsuitable for transplantation, and the organ retrieval process is stood down, then the SN should consider existing contact arrangements agreed with the patient's family for communication.

10.3. COMMUNICATING TO A FAMILY ANY POST DONATION FINDINGS REQUIRING ADDITIONAL ACTION

10.3.1. The SN should utilise New Clinical Information Post Retrieval but Pre Transplantation and/or New Clinical Information Post Transplantation section of the manual for guidance and direction on the actions to take if a finding requiring additional action is identified following the organ retrieval process.

10.3.2. If a specific organ has been declined due to a finding requiring additional action post donation, yet other organs are retrieved and implanted, then the SN should communicate the outcome of the

donation through the normal communication pathway agreed with the patient's family. This will have been agreed with the patient's family as part of the consent/authorisation process.

10.3.3. If all organs and/or tissues have been found to be unsuitable for transplantation at the recipient centre, or that an adverse finding has been identified post implantation, then the SN should consider existing contact arrangements agreed with the patient's family for communication. The SN should also follow points of this process to inform the family that organ and/or tissue donation was unable to proceed and document discussion in DonorPath in Sequence of Events.

11. STATUTORY NOTIFIABLE DISEASES

Section Contents - Hyperlinked

	Manual Index
11.1	Managing and Sharing Information Regarding Statutory Notifiable Diseases
	Associated Documents and References (A-Z)

11.1. MANAGING AND SHARING INFORMATION REGARDING STATUTORY NOTIFIABLE DISEASES

11.1.1. The SN should communicate with the Medical Practitioner in the donor hospital and confirm if the finding is a suspected/confirmed **statutory notifiable disease/infection** and therefore, potentially transmissible and contact the ODST Lead Nurse/geographical Regional Head of Nursing / ODLT On-Call for advice and support, as required.

11.1.2. The Medical Practitioner must report any suspected or confirmed statutory notifiable disease to an Expert Practitioner in Public Health, as per the relevant geographical reporting process, and initiate local investigation and control measures as part of their professional duties:

England & Wales

11.1.3. In England and Wales, the statutory notifiable disease **INF958** must be reported to a Proper Officer of the Local Authority-Health Protection Unit, who in turn report to the Health Protection Agency.

Scotland

11.1.4. In Scotland the statutory notifiable disease **INF960** must be reported to the Health Boards, who in turn report to Health Protection Scotland (HPS).

Northern Ireland

11.1.5. In Northern Ireland the statutory notifiable disease **INF961** must be reported to the Consultant in Communicable Disease Control (CCDC) or Duty Public Health Doctor and the Infection Control Team.

11.1.6. The SN must work closely with the Medical Practitioner in determining any potential risk to the patient's family members. If needed, expert advice must be sought from an Expert Practitioner in Public Health to advise on the correct course of action to take.

11.1.7. The SN should assist the Medical Practitioners, if appropriate, in providing any information they have gained during the consent/authorisation and patient assessment process. This information could include new information regarding close relationships that determine any potential transmission/infection risk from the patient to others.

11.1.8. The attending Medical Practitioner should fill out a notification certificate immediately on diagnosis of a suspected statutory notifiable disease and should not wait for laboratory confirmation of the suspected infection or contamination before notification. The certificate should be sent to appropriate Expert Practitioner in Public Health within three days or verbally within 24 hours if the case is considered urgent.

11.1.9. It is permissible to breach patient confidentiality by reporting statutory notifiable disease/s to the relevant authority where there is an overriding public interest. This is confirmed in the NHS Code of Practice: Confidentiality (DoH, 2003):

"There are exceptions to the duty of confidence that may make the use or disclosure of confidential information appropriate. Statute law requires or permits the disclosure of confidential information in certain circumstances……Case law has also established that confidentiality can be breached where there is an overriding public interest"

12. ADDITIONAL INFORMATION FOR HUB OPERATIONS PROCESS

Section Contents - Hyperlinked

	Manual Index
12.1	Live Donors/Donors from Outside the UK
12.2	Verbal reports
12.3	Written reports
12.4	Photographs
12.5	Transport Fluid reports
12.6	Other Ad-Hoc Reports
	Associated Documents and References (A-Z)

ⓘ ADVICE

Hub Operations must use the STOP, PAUSE, CHECK process when managing clinical information.

At all times it is important that Hub Operations share the information with the SN's in the first instance and wait for further information regarding how to proceed. If new information is received by Hub Operations with insufficient PID standards, this must be forward to the Regional SN immediately via email to assist in obtaining correct PID.

It is the SN's responsibility to ensure clinical information is shared and therefore imperative that all clinical information is reviewed by SN's before sharing the information with receiving centres and/or before organs are offered on. On all occasions if a clinical conversation is required this must be undertaken by the SN directly.

12.1. LIVE DONORS/DONORS FROM OUTSIDE THE UK

Live Donors:

Hub Operations may at times receive a completed copy of **FRM5964** Transport Fluid Alert Form for a live donor.

Hub Operations will not be able to locate these donors on NTxD and will therefore need to contact the LKD (Living Kidney Donation) Team to ascertain which centre received an organ from this donor. This can be done by emailing LKDschemes@nhsbt.nhs.uk and providing all the information so the correct donor can be identified.

Report received from receiving centre: No further action is required, and the email can be moved to the actioned folder.

Report received from the donating centre: This will need to be shared with the receiving centre as per the section below on Transport Fluid reports

Donors from outside the UK:

Dublin or European centres may obtain further clinical information after an organ has been sent to and transplanted by a UK centre.

This information can be shared directly with any receiving centres and **does not** need to be shared with any SN's first. If the centre requires further information, they will need to contact the Dublin or European contact that the information has been received from.

12.2. VERBAL REPORTS

Clinical information regarding solid organ donors may only be available in verbal form while a written report is being produced. In all cases it is essential that the details of the clinician are taken and that these details are urgently passed onto a SN from the relevant regional SN team that were in attendance with that donor. The SN will then contact the clinician to discuss the information.

At all times, a minimum of 3 points of PID must be confirmed as per **MPD1086** to ensure that the information is recorded against the correct donor and that the correct relevant parties are informed.

It is the responsibility of the SN to advise on the cascade of information. In these circumstances when a verbal report of clinical information is received, the process below must be followed to ensure that all receiving centres promptly receive information relevant to the safe management of their recipients:

1. Call received from a receiving centre to advise that they have a verbal report to relay.
2. Hub Operations will need to advise the caller that this information must be shared with the SN and ask for their name, contact details and location, and inform the caller that an SN will call them back to discuss.

No information should be sent to other receiving centres until further discussion with the SN.

If organs are declined, reoffering should not commence until further discussion with the SN.

3. SN to contact the caller and discuss the information available. If this requires a clinical explanation, then the SN will be responsible for contacting all other receiving centres.
4. The SN will need to update DonorPath with the information received.

If the information does not require a clinical explanation, the SN can request that Hub Operations contact all receiving centres to advise that an update has been made to a specified section of CDD and that this update can be viewed in TransplantPath by following the below steps:

- Contact all receiving centres via the contact method on the Digital Directory (if organs have been placed for research, this information must also be given to the accepting researcher).
- Ensure that they provide details of the donor to which the new clinical information relates to using a minimum of 3 points of PID (as per **MPD1086**).
- Advise the receiving centre where the information can be located e.g. on TransplantPath and in which section. No information should be relayed verbally.
- Using the note template available on the Digital Directory (Histopathology/Virology/Microbiology/Photos note template) record in NTxD in the relevant donor's notes all centres and the contact's name of the person that has been informed of this information.

ⓘ ADVICE

For any organs that have been accepted by any Transplant Organisation in Europe, the report (or alternative written documentation provided by the SN) will be emailed to the Hub Operations inbox. Hub Operations will be responsible for forwarding this information to the receiving European centre. SN's will not be responsible for communicating this information. In all cases, all details must be documented onto the relevant donor's notes including who the information was sent to and that a call was made to confirm receipt.

12.3. WRITTEN REPORTS

The safest way to communicate clinical information is in writing and written versions of all clinical information received verbally should be sought at the earliest opportunity. It is the responsibility of the Regional SN Team to ensure that written reports are followed up.

ⓘ ADVICE

This guidance applies to all clinical information received EXCEPT for transport fluid reports – for guidance on these reports, see here

The below process must be followed to ensure that the receiving centres have written confirmation to support any information relayed verbally.

New information uploaded to TransplantPath:

As information can now be uploaded to TransplantPath, there is no requirement for this to be sent to Hub Operations to communicate out unless in the instance of an IT outage. If information has been uploaded to TransplantPath, please see the below steps for guidance on this process:

- The receiving centre will upload the information to TransplantPath and then call Hub Operations to confirm that this has been completed.
- Hub Operations staff will need to add a note to the relevant donor record in NTxD to confirm that new information is available.
- Once a note has been added to NTxD, Hub Operations will need to contact the SN team to advise of the new information.
- A discussion will then need to be had between Hub Operations and the SN to agree how this information will be cascaded to any other receiving centres that need to be aware.

New information received via email:

If there is a system outage or the TransplantPath user is unable to access the system, the only way that this information can be safely shared between all parties will be for this to be communicated via email. For this process, please see the below steps:

- An email will be received in the Hub Operations inbox, and a call should be made to Hub Operations from the sender to confirm that this has been received.
- A note will need to be added to the relevant donor record in NTxD to confirm that this has been received.
- The email containing the information will need to be checked for a minimum of 3 points of PID (Patient Identifiable Data) to locate the donor in NTxD and to confirm which SN team this will need to be shared with. As per **MPD1086**, if there is not 3 points of PID available, please use what PID is there to locate the donor. The SN will be responsible for checking the PID and getting the relevant information added to the report if it is not there.
- The information received will need to be added to the electronic donor file in the F Drive for use if Hub Operations are asked to forward this on to any other receiving centres.
- The information received will need to be sent to the regional SN team and a call made to the team to confirm receipt.
- It will be the SN's responsibility to upload this to DonorPath if the system is still available and not affected by the outage.
- A discussion will then need to be had between Hub Operations and the SN to agree how this information will be cascaded to any other receiving centres that need to be aware.

How the information should be shared with each centre:

If the SN confirms that Hub Operations can share this information, then for each centre the OAS should:

- Contact all centres via their preferred method of contact from the Digital Directory and confirm that new information has been uploaded to TransplantPath and where this can be viewed. This should be handed over verbally so therefore if a centre is contacted via pager, they must be paged to call into Hub Operations to receive the update. If the information has been emailed to them due to a system outage, Hub Operations will need to inform them of this and confirm that it has been received.
- Using the note template available on the Digital Directory (Histopathology/Virology/Microbiology/Photos note template) record in NTxD in the relevant donor's notes all centres and the contact's name of the person that has been informed of this information.

***Note:* If a report needs to be sent to the NRC, this will need to be sent to:**
National.referralcentre@nhsbt.nhs.uk

12.4. PHOTOGRAPHS

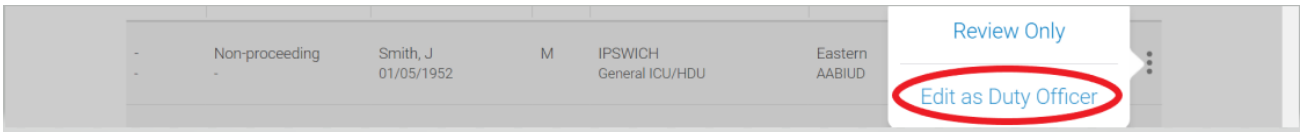
When an organ needs to be allocated after having been retrieved, an SN may take photographs of the organ for Hub Operations to share with considering receiving centres to aid decisions around acceptance or decline of an organ. The SN can upload these images to DonorPath (as per **SOP6651 OTDT Manual 11**) so that they can be viewed in TransplantPath by all receiving centres.

SN's should inform Hub Operations if photographs are available.

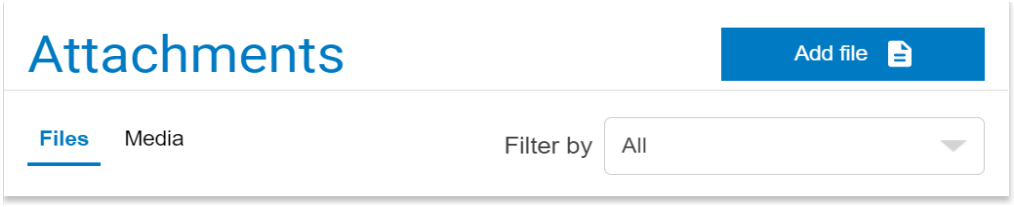
If photographs are taken by a receiving centre, these can now be uploaded to TransplantPath. The centre will need to inform Hub Operations that this has been done.

If a centre is unable to upload these images due to an outage, Hub Operations can upload them to DonorPath if this is still operational by following the below steps:

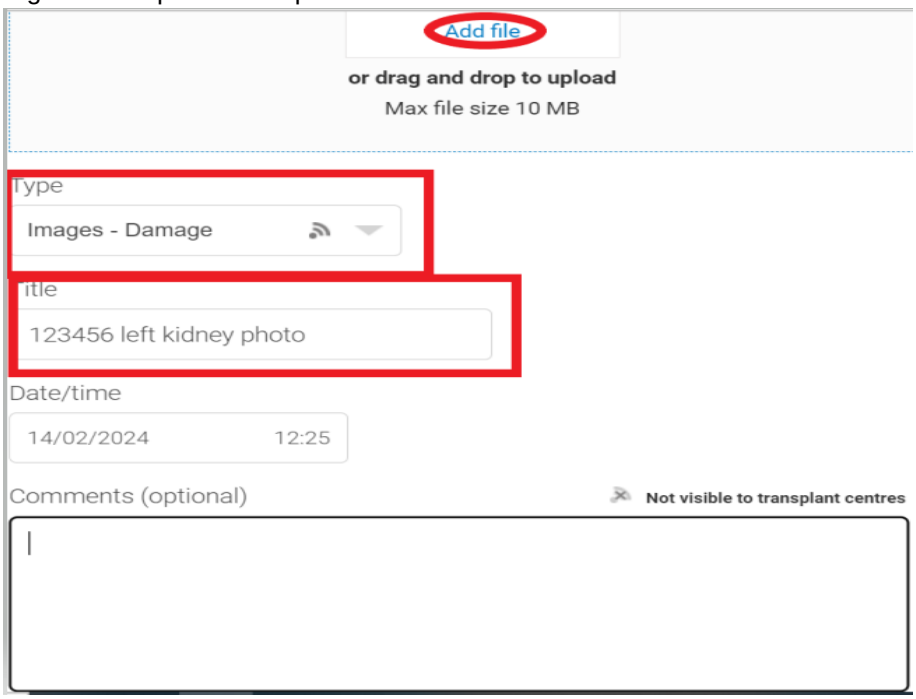
- Log into DonorPath.
- Using 3 points of PID, locate the relevant donor.
- Once the correct donor has been identified, click on the 3 dots on the right-hand side of the screen and select 'Edit as Duty Officer' as per below screenshot:



- Once inside the donor record, select 'Pathway' as the option at the top of the screen and locate 'Attachments'
- Once inside Attachments, select 'Add File' as per below screenshot:



- Once you have done this, a box will appear for the photographs to be attached to. You can click 'Add File' and select the file that needs to be uploaded. The 'Type' dropdown must be changed to 'Images – Damage' and the file must be titled with the donor number and confirmation of the organ that is pictured as per below screenshot:



- If organs require fast-tracking from this point, centres can be informed that new images are available for viewing in TransplantPath.
- If there is a full system outage, the expectation will be that the centre emails the images to Hub Operations who can store them in the electronic donor file and disseminate where required (i.e., if fast-tracking an organ that has been declined).

12.5. TRANSPORT FLUID REPORTS

ⓘ ADVICE

There is no need to share this information with any SN Teams before sending out to the relevant centres as with other reports as these do not require a clinical conversation.

Receiving centres will now be able to upload Transport Fluid Reports onto TransplantPath for viewing. When doing so, they need to call Hub Operations to advise that the information is available. As any other receiving centre will not know that this information has been uploaded, Hub Operations will need to contact them to advise that there is new information available on this donor record.

In the case of a system outage, these reports will be emailed to Hub Operations for dissemination. These will be sent using **FRM5964** and Hub Operations will only process these reports when they are

received in this format. Any received in a different format will be returned to the sender with a request to re-send using the correct form.

On receipt of this information, Hub Operations staff will need to follow the below steps:

- Establish the identity of the donor using a minimum of 3 points of PID (as per **MPD1086**).
- Ensure that the form itself contains a minimum of 3 points of PID – if not, the sender must be contacted and asked to re-send the form with the correct PID.

A copy must be saved to the relevant donor's electronic file in the F Drive.

This information will need to be shared with all receiving centres by following the below steps:

- Establish which receiving centres require a copy of the report using **FRM4207** and the Organ Outcome page in NTxD (including any relevant researchers if any organs were accepted for research).
- Forward a copy of the report via email to all receiving centres that have received an organ from the donor, NRC and SNBTS (for donors in Scotland) using the email addresses listed in the Digital Directory (this information can also be found in **DAT2792**).
- A note must be entered onto the relevant donor's notes in NTxD using the Transport Fluid Reports note template on the Digital Directory confirming who sent the form into Hub Operations and who this has been shared with.
- **For these reports, there is no requirement to telephone receiving centres to confirm receipt if sent to centres during a system outage.**

12.6. OTHER AD-HOC REPORTS

For any other reports that are received into Hub Operations, a conversation will need to be had with the Regional SN Team to see if this is a report that needs to be forwarded to receiving centres and whether this will need a clinical conversation.

ASSOCIATED DOCUMENTS AND REFERENCES (A-Z)

ABBREVIATIONS & GLOSSARY:

INF1277 - Abbreviations
INF1693 - Glossary of Terms for Deceased Organ and Tissue Donation and Transplantation in the UK

DOCUMENTS:

DAT2792 - Recipient Centre Point of Contact – List of email addresses
DAT4135 - Researchers – Contact list email addresses
DAT4183 - Examples of Good Documentation Practice
FRM4193 - Core Donor Data - SNOD (Used as EOS back-up)
FRM4207 - Core Donor Data Form – Hub Operations
FRM4211 - Medical and Social History Questionnaire
FRM5499 - SN to DFCS Handover Form
FRM5545 - Body Map
FRM5867 - National Histopathology Request Form
FRM5964 - Transport Fluid Alert Form
FRM6342 - General Practitioner Medical Report for Organ/Tissue Donation
FRM6390 - National Histopathology Request Form for Use at Transplant Centres
FRM6439 - SARS-CoV-2 Assessment and Screening (in deceased organ donors)
FRM7726 - Microbiology Request Form at retrieval
INF958 - Statutory Notifiable Diseases England and Wales
INF960 - Statutory Notifiable Diseases Scotland
INF961 - Statutory Notifiable Diseases Northern Ireland
MPD1043 - National Standards for Organ Retrieval from Deceased Donors
MPD1086 - Patient identifiable data
MPD385 - Guidance on Good Documentation
POL188 - Clinical Contraindications to Approaching Families for Possible Organ & Tissue Donation
SOP3888 - Reporting an Organ Donation or Transplantation Incident to NHSBT
SOP5049 - OTDT Manual 8: Post Donation and Family Care
SOP5499 - OTDT Manual 4: Offering and Retrieval
SOP5685 - Ad-hoc Tissue Requests of Blood Vessels and Rectus Fascia from Deceased Organ Donors
SOP6405 - OTDT Manual 1: Referral and Characterisation
SOP6514 - OTDT Manual 3: Clinical Microbiology
SOP6651 - OTDT Manual 11: Operational Process Support

REFERENCES:

SaBTO guidance on the microbiological safety of human organs, tissues and cells used in Transplantation:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_121497

TRAINIG PLAN FOR DOCUMENT:

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 and OAS will require full training to this document by their ODST Quality Lead SN and Foundation Training programme or Practice Development Lead in Hub Operations of the OAS team.	SNs / OAS previously trained to SOP4938 can receive training via recorded author presentation delivered by their regional Quality Lead SN. Practice Development Lead in Hub Operations to deliver training for of the OAS team.
Knowledge required prior to training	Full training of SOP.	Trained to previous version.
Critical aspects of process	The purpose of this SOP is to provide a clear guidance on findings requiring additional actions and communication pathway for the SN (Specialist Nurse) and OAS (Organ Allocation Specialist) on clinical assessment and action to be taken when any new clinical information comes to light at any point during the donation process. It is imperative to ensure all receiving centres are informed of the new clinical information in as timely a manner as possible ensuring that where required a clinical conversation led by the SN takes precedent. New clinical information can come to light at any point in the deceased donation process from referral to post implantation/transplantation. In all circumstances it is essential that any new information is considered in a clinical context taking into consideration the wider communication required and the potential impact of the clinical finding on other receiving centres who have received or may receive organs or tissues from the same donor.	

Training Plan:

	Trainee new to the process	**Trainee trained to the previous revision.**
Recommended Training Method	Practical demonstration and read through the document with Regional ODST Quality Lead. Training material for this version will not cover the whole SOP content. Practice Development Lead in Hub Operations to deliver training for of the OAS team.	Train out via standardised video from SOP Author to ODST Regional Quality Leads train to TBTR. The same video can be disseminated via QLs and record TBTRs Practice Development Lead in Hub Operations to deliver training for of the OAS team.
Assessment	TBTR Training Record	FRM511 or FRM5281
Cascade Plan	Collaborative practical demonstration and read through the document with Regional ODST Quality Lead and Practice Development Specialist.	Train out via standardised video from SOP Author to ODST Regional Quality Leads train to TBTR. The same video can be disseminated via ODST QLs and record TBTRs

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**: (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**: (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: (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: (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	4

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	3

Training Plan Risk Matrix:

Process Criticality →

Criticality of Change ↓

	1. Negligible	2. Minor	3. Moderate	4. High	5. Very High
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

	Trainee new to the process	**Trainee trained to the previous revision.**
Process Criticality Score	**4**	
Criticality of Change Score	**4**	**3**
Training Score	**16**	**12**

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