Blood and Transplant
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OTDT MANUAL 6:

Judicial Process

Index

IMPORTANT:

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

SUMMARY OF CHANGES

This is a brand-new manual. While much has been moved from the previous documents (MPD865 & SOP6458), there are new additions and the flow of the process in the document has altered. Therefore, this document should be reviewed in full as part of its training.

This document is now the primary controlled document for the following controlled documents:

- **DAT4440** – Coroner Referral Proforma – England, Wales and Northern Ireland Participating Hospitals
- **FRM4039** – NHSBT Referral for Coroner/Procurator Fiscal
- **FRM7248** – Coroner Referral Proforma - England, Wales and Northern Ireland
- **FRM7249** – Local Coronial Agreement for Organ Donation Referral Process
- **INF1685** – Guidance for Coroner Referral Proforma – England, Wales and Northern Ireland

The following documents will become obsolete on the effective date of **SOP6633**:

- **FRM6110** – Coronial Lack of Objection for Organ/Tissue Donation Request
- **MPD865** – Obtaining Coroner/Procurator Fiscal Decision
- **PDV1087** – PDV against MPD865
- **PDV1278** – PDV Against MPD865 - Medical Examiner Guidance
- **SOP6458** – Completion of Electronic Proforma Referral to Coroners

INTRODUCTION

BACKGROUND

The Coroners and Justice Act 2009 is a UK Act of Parliament that significantly reformed the coroners' system and made various changes to criminal justice law in England and Wales. Key reforms included a new framework for coroner investigations, with a focus on putting bereaved families at the centre, updating criminal law, including provisions on diminished responsibility and loss of control in homicide cases, and improved witness protection. The Crown Office and Procurator Fiscal Service (COPFS) is Scotland's prosecution service, responsible for deciding whether to prosecute criminal offences and for investigating all sudden, suspicious, accidental, unexpected, and unexplained deaths.
Organ and tissue donation should only occur after all requirements relating to authorisation or absence of any objection currently in force within the Member State have been met.
The Criminal Justice Act 2003 introduced a series of reforms to the UK's criminal justice system, focusing on court procedure, offence allocation, and sentencing. The Coroners and Justice Act 2009 does not apply to Scotland, though certain provisions related to coroners and investigations of deaths are specifically adapted to the Scottish context and supported within The Criminal Justice (Scotland) Act 2016.

In England and Wales, all deaths should be scrutinised by the Medical Examiner (ME) as per the donor hospital procedure and allows for ME discussion before organ and tissue retrieval, unless the case meets the criteria for coroner referral. The Medical Certificate of Cause of Death Regulations 2024 define practice standards and the new medical certificate of cause of death (MCCD) to be used by attending practitioners and ME since 9th September 2024. This creates a responsibility for ME to provide independent scrutiny of non-coronial deaths.

However, in the United Kingdom, in some circumstances it is necessary for the Coroner or Procurator Fiscal (PF) to determine if an objection to solid organ, tissue donation and removal of relevant material for research or scheduled purposes, will be raised.
The Coroner/PF has a legal requirement to do this, and must be satisfied that neither organ, tissue nor removal of organs for other/scheduled purposes will impede the investigation and the Coroner/PF has the final decision of what can be donated/retrieved.

Therefore, the Specialist Nurse (SN) must ensure that, to the best of their knowledge, all relevant information is relayed to the Coroner/PF Office so that they may plan in relation to raising an objection (consent in Scotland) to organ, tissue donation and removal of organs for other/scheduled purposes proceeding.

In any case where the Coroner/PF or Police are involved, the Coroner/PF has the final decision of which organs and tissue can be donated/retrieved. To assist the Coroner/PF to make that decision, the SN and the medical team has an essential role in undertaking a detailed review of the circumstances surrounding the death of the potential donor. For tissue only referrals facilitated by Clinical Administration Team (CAT) within tissue donation, other members of the MDT will support in gaining required information.

ADVICE

If an ME or Clinician decides not to refer a case to the Coroner/PF, it is their decision. However, if the SN believes a referral is needed, they should discuss it with the clinician using resources in Appendix 1 to demonstrate the concern. If the clinician still decides not to refer and the SN disagrees, they should consider escalating to LN/OMT On Call.

ADVICE

If DonorPath is unavailable, then **FRM4039** - Referral Form for Coroner/Procurator Fiscal must be completed in full. The Coroner/Procurator Fiscal lack of objection information must be included on **FRM4193** if **SOP3925** is implemented.

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.
Incidents should be reported to the OTDT Patient Safety team via the Incident Submission Form

SECURE EMAIL

Secure email is between NHSBT accounts or between NHSBT to nhs.net and between nhs.net accounts. Full Data Protection Impact Assessment (DPIA) have been reviewed and confirm the SN is permitted to email information, including **FRM7248**, to a Coroner/Coroner Officer via @NHSBT.nhs.uk to GOV.uk or eJudiciary.net only.

If there is any IT failure or issues stopping correspondence via email between NHSBT.nhs.uk to GOV.uk or eJudiciary.net email addresses, the SN and Clinician must ensure the details of the judicial decision request and receipt of the Coroner/PF donation decision is verbally received and documented in the patient's medical notes and within DonorPath.

The SN **MUST NOT** share information by email, including **FRM7248**, if a coroner's jurisdiction GOV.uk or eJudiciary.net email is not able to be used.

ROLES

Specialist Nurses Organ Donation / Specialist Requester / Family Care (SN), Specialist Nurses Tissue Donation (SNTD), Lead Nurses (LN) of Organ Donation Services Teams and NRC and Clinical Administration Team (CAT)

- To ensure the local Medical Examiner (ME) practices are followed in scrutiny of the Medical Certificates of Cause Death (MCCD).
- To ensure that the retrieval of organs and/or tissue donation and removal of organs for other/scheduled purposes only occur following Coroner/Procurator Fiscal lack of objection to donation, where appropriate.
- To ensure that all necessary information pertaining to the potential donor's admission has been obtained and communicated to the Coroner/Procurator Fiscal office to ensure that an informed decision has been made, either directly or via the responsible healthcare professional in the hospital. This includes collaboration with other professional agencies, such as Police or Pathologist.
- To ensure Coroner/Fiscal permissions are gained to move the deceased from their place of death to the dedicated tissue donation facility.
- To document the decision made by medical team and Coroner/Procurator Fiscal.

Responsible Medical Professional (Clinician)

- Doctor with delegated responsibility from the clinician in charge of the patient's/potential donor's care.
- Support the SN in the facilitation of telephone discussion between the Donor Hospital teams and a Coroner/Coroner Officer as required.

Operational Management Team On Call (OMT On Call)

- Provide advice to SN/Clinical Teams regarding Coroner/PF process.

Associated Documents

- **DAT4440** – Coroner Referral Proforma – England, Wales and Northern Ireland Participating Hospitals.
- **FRM1014** – Cause of Death Confirmation
- **FRM4039** – NHSBT Referral for Coroner/Procurator Fiscal
- **FRM4193** – Core Donor Data - SNOD (Used as EOS back-up)
- **FRM6029** – Provisional Cause of Death for Ocular Files
- **FRM7248** – Coroner Referral Proforma – England, Wales and Northern Ireland
- **FRM7249** – Local Coronial Agreement for Organ Donation Referral Process
- **INF1685** – Guidance for Coroner Referral Proforma – England, Wales and Northern Ireland
- **MPD845** – Family Care
- **POL188** – Clinical Contraindications to Approaching Families for Possible Organ & Tissue Donation
- **SOP3925** – Manual Organ Donation Process for Potential Organ and/or Tissue Donor in the event of DonorPath/IT network unavailability
- **SOP4938** – Sharing Clinical Information
- **SOP5874** – Paediatric Manual
- **SOP6079** – Deceased Donor File Administration -TissuePath

1. REVIEW BY MEDICAL EXAMINERS (ME) – England and Wales Only


England & Wales

A discussion should occur with the hospital Medical Examiner (ME) to confirm if a death or expected death requires referral to HM Coroner. This is to ensure a lack of objection decision for organ and/or tissue donation is sought from the HM Coroner in appropriate cases before retrieval of organs and/or tissues.

Discussion with the ME before organ and tissue donation is a risk-based approach, designed to try to reduce the risk of an unnatural element and subsequent coroner referral only being discovered after retrieval has taken place. This discussion can take place prior to completing full scrutiny.

Obtaining an accurate account of the circumstances surrounding the patient's admission, course of illness, diagnosis, medical and surgical procedures and/or investigations and medical history from the medical team and nursing staff is a crucial first step in determining a detailed history. The discussion with the ME for consideration of referral to HM Coroner should focus on:

a) What is the proposed cause of death?
b) Is the clinician aware of any reasons for Coroner referral?
c) Are there any clinical concerns around care?
d) Are there any family concerns around care?

NB: ME advice is not mandatory and the ME service is unlikely to be available 24/7 in every hospital trust/health board.
Only if a ME is not available, the SN and Clinical Team may proceed without ME advice if both the SN and Medical Team conclude the expected death does not meet The Notification of Death Regulations (2019). The death must still be reported to the hospital ME as per donor hospital process when the ME becomes available.

For safe and considered organ and/or tissue donation, the following process steps are advised:

1.1. Firstly, follow any local agreement that is in place with the Trust/Board ME and HM Coroner service regarding organ and tissue donation.

1.2. If there is no local agreement:

1.2.1. There should be a discussion with the ME prior to organs and/or tissues being retrieved to indicate if HM Coroner referral must occur. As per National Medical Examiner's Good Practice Series No. 4: Organ and tissue donation (NMEGPS4), this discussion can take place before an expected death and prior to completing full scrutiny after death. A record of discussion must be documented in DonorPath / TissuePath Sequence of Events (SoE) and any written evidence uploaded.

1.2.2. If there is no ME available despite all practicable efforts, and the case clearly meets The Notification of Death Regulations (2019), then referral to the Coroner for a lack of objection decision must occur.

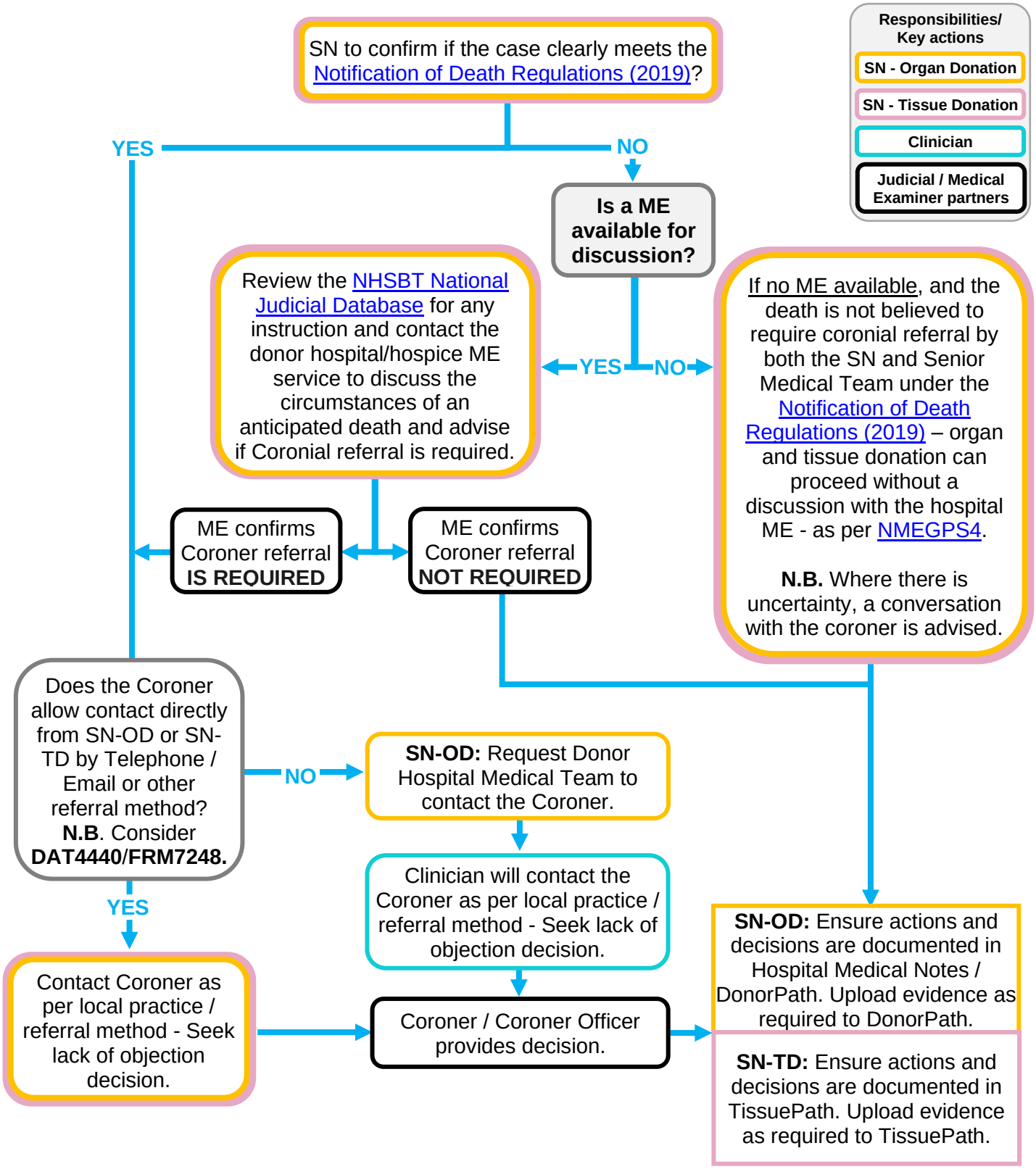
1.2.3. If no ME is available despite all practicable efforts and the death is not believed to require coronial referral by both the SN and Senior Medical Team under The Notification of Death Regulations (2019) – organ and tissue donation may proceed without a discussion with the hospital ME as per NMEGPS4.

1.2.4. If no ME is available despite all practicable efforts before the point of organ offering/tissue donor approach, and both the SN and Senior Medical Team are uncertain of the requirements for coroner referral, a conversation with the coroner is advised.
(NHSBT Risk Register: OTDT 07 and ODT 40)

PROCEDURAL DIAGRAM FOR MEDICAL EXAMINER REVIEW

England & Wales

N.B: This guidance applies to donors in England and Wales only. Where there is no local agreement in place with the trust/Board Medical Examiner (ME) and HM Coroner service regarding organ and tissue donation.



2. REFERRAL TO CORONER / PROCURATOR FISCAL (PF)

2.1. For donor hospital specific guidance on Coroner/Procurator Fiscal (PF) referral – please consult the NHSBT National Judicial Database, located in the Judicial Process SharePoint.

2.2. The SN or Clinical Team should contact the Coroner/PF Office, where possible, early in the donation process during working hours. This will allow for the Coroner/PF to be contacted more easily and enable an informed and timely decision to be made. It will also allow for the judicial offices to have discussions with other Coroners/PFs, where the initial injury/incident may have occurred outside their jurisdiction or to the relevant Police forces and/or Pathologists to discuss the case in further detail. Early discussion with the Coroner/PF is supported in Coroner/PF external guidance (see Appendix 1.5 and Appendix 1.6)

2.3. Where there is suspicion of complex decision making that would require the Coroner/PF to liaise with Police and/or Pathologists, the referral to Coroner/PF should occur before approaching donor NOK for organ and tissue donation. This will support multi agency professions time to consider the decision.

2.4. Contacting a Coroner/PF outside of working hours is only appropriate in the unlikely scenario where the referral is received out of hours, and the retrieval needs to take place out of hours during that same window of time (i.e., the same night/weekend). The SN and Clinician must be available to answer any questions.

2.5. Every referral to the Coroner/PF must include the request for each relevant organ and tissue transplantation or research, and must include the following core requests for organ and/or tissue donation:

a) Lymph, spleen and blood vessels
b) Surrounding Tissue will be removed to support the safety and quality of transplantation. Only where necessary, this will include part or whole organs.
c) Novel technologies that require access to organs and/or tissue not listed in the request.

2.6. All relevant details, including contact information of SN, patient demographics, admission details and events in hospital as well as Police details should be given.
A non-exhaustive list of examples could be:

a) Safeguarding concerns
b) Trust/Health board investigations
c) Family concerns / complaints.
d) In hospital untoward incidents

2.7. The SN should also confirm if the Coroner/PF has a requirement for admission blood samples and if there is likely to be a postmortem or Forensic involvement. If there is a Forensic interest, please note that hairlocks, other keepsakes and final cares may be restricted by the Coroner/PF, Police or Pathologist and Police escort may be required from the time of death. This should all be discussed and confirmed at time of final Coroner/PF decision.

2.8. The SN should ask the Coroner/PF or their officer if they are able to give a timeframe for a decision to be reached. If there are significant delays and a pause in the process is not possible, consider setting up the organ donation process pending Coroner/PF decision. In exceptional circumstances only, organs can be offered pending the final decision unless a forensic postmortem examination is likely. In this circumstance, the SN must escalate to OMT On Call for a decision regarding progressing to offering. NORS should not be mobilised until a lack of objection from the Coroner/PF is received.

2.9. If the timeframe for a decision has elapsed, and it is deemed appropriate, then the SN should contact the Coroner/PF or their officer for further advice.

⚠ CAUTION

If offering prior to the Coroner/PF final decision, ensure this is clearly documented in the visible Coroner/Procurator Fiscal box within the **Consent Section** of DonorPath to inform the Recipient Point of Contact (RPoC) as part of the organ offer and retrieval planning - via TransplantPath.

DIGITAL PROFORMA

REQUIREMENTS FOR POPULATING AND SHARING FRM7248 - CORONER REFERRAL PROFORMA FOR THE CORONER/CORONERS OFFICER

2.10. The details of which hospitals and coroner jurisdictions that **FRM7248** can be used for are listed in **DAT4440**. The SN must check **DAT4440** before every potential donation request to a Coroner and follow agreed process. If the potential donor is not in a participating donor hospital that aligns with coroner jurisdiction, revert to practice as per previous section.

2.11. If the potential donor is being cared for in a donor hospital listed in **DAT4440**, the SN must inform the Clinician in charge of the potential donor's care that **FRM7248** will be used.

2.12. Following assessment of the potential donor case and discussion with clinical team in charge of the potential donor's care, the SN must populate all required sections of **FRM7248** (see section Appendix 3 for guidance).

2.13. Following final checking of **FRM7248** for accuracy and confirming contact preferences listed for the coroner jurisdiction, prepare to contact the Coroner/Coroner Officer by telephone.:

SN CONTACT: Ensure the corresponding regional ODST NHSBT Email Address is listed on **FRM7248**. Contact with the Coroner/Coroner Officer by telephone to advise use of the Coroner/PF donation decision request with a brief summary of circumstance. Agree to share **FRM7248** for review and to be returned with the documented lack of/partial/full objection. **FRM7248** can only be emailed to a GOV.uk or eJudiciary.net email only. The SN MUST NOT share **FRM7248** if a coroner's jurisdiction GOV.uk or eJudiciary.net email is not being used (if unable, refer to section 3)

CLINICIAN CONTACT: If initial contact is to be made by the clinician, ensure the clinician follows the same steps as above and the requirement to make coroner contact together. This enables contact details to be gained for sharing **FRM7248** and answer/clarify any questions.

2.14. Email the **FRM7248** Proforma to the confirmed GOV.uk or eJudiciary.net email address with an appropriate email subject and background request. **INF1685 c**an be shared with the Coroner/Coroner Officer for any support with the request.

3. RECEIPT OF JUDICIAL DECISION

ADVICE

Referral to the Coroner/PF should be a collaborative effort between the SN, Clinical team, and Medical Examiner. If the Clinical Team has contacted Coroner/PF and obtained the decision prior to SN involvement, it must be reviewed to ensure it covers all aspects of the donation case (e.g. all applicable organs and tissues requested, novel transplantation, research and body transfer).

3.1. The language to be used when referring to the decision of a Coroner/PF should be as follows:

- **A Full Lack of Objection decision** (e.g. no organ and/or tissue requested have been restricted by the Coroner / PF).
- **A Partial (restricted) Objection decision** (e.g. only some and not all requested organs and tissues, have been restricted by the Coroner / PF)
- **A Full Objection decision** (e.g. The process of organ and tissue retrieval cannot proceed).

The SN must be aware of the internal system categories and how to accurately reflect the decision of the Coroner/PF in DonorPath for organ and tissue assessment/offering, and Potential Donor Audit (PDA):

DonorPath / PDA Categories	Correct Language
Yes - Full Consent / Authorisation	**A Full Lack of Objection decision**
Yes – Restricted Consent / Authorisation	**A Partial (restricted) Objection decision**
No	**A Full Objection decision**

3.2. Evidence required to document a Coroner/PF decision are as follows:


England & Wales


Northern Ireland

3.2.1. **England, Wales and Northern Ireland:** Documenting the final decision differs between jurisdictions. In all cases, the SN should attempt to gain the final Coroner decision in writing via email. If attempts gaining written confirmation from the Coroner is not possible, the person who had the conversation with the Coroner should document their conversation and the final decision clearly within the medical records.


Scotland

3.2.2. **Scotland:** Written confirmation from the Procurator Fiscal involved is required under the Human Tissue (Scotland) Act 2006 as soon as is practicably possible. Usually this is emailed to the SN and must be uploaded to DonorPath in the attachments section.

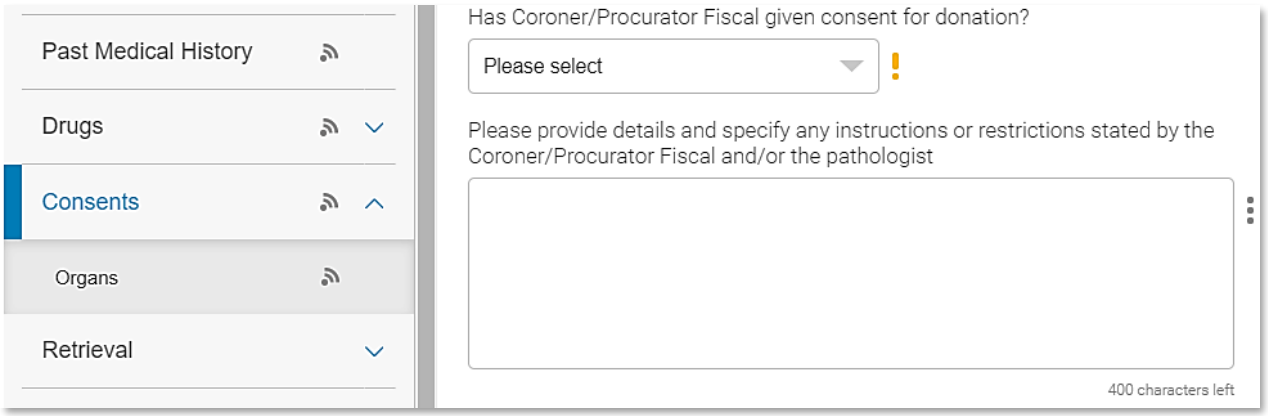
USE OF CORONER / PROCURATOR FISCAL REFERRAL AND DECISION DOCUMENTATION

3.3. If the clinician has spoken to the Coroner/PF in relation to donation, the clinician should clearly document this, detailing the lack of objection and which organs and tissues can be retrieved for transplant and other/scheduled purposes, detailing any restrictions, special requirements or requests. The SN must ensure that a copy of the clinician's medical entry is uploaded to DonorPath. Details of the Coroner/PF conversation must be recorded on DonorPath in the Coroner/PF section.

3.4. In instances where a Coroner/PF decision is obtained prior to family discussions, the outcome of these conversations in respect to consent/authorisation for organ, tissue donation and removal of organs for other/scheduled purposes should be communicated to the Coroner/PF. There may be some regions with specific Coronial/PF requirements in relation to Donation after Circulatory Death.

3.5. Following a lack of objection from the Coroner/PF, if any new information is received regarding the circumstances surrounding a patient's death or should there be any change in the details of the donation (e.g. conversion between DCD or DBD where additional organs may be offered for donation), this information should be communicated to the Coroner/PF and additional lack of objection sought. Details of these additional discussions with the Coroner/PF must be recorded on DonorPath in the Coroner/PF section.

3.6. Prior to donor registration, ensure any restrictions are clearly documented in the Coroner/PF free text box within the Consent section of DonorPath (image below). This is the only visible Coroner/PF section for NORS/RPOCs via TransplantPath and will allow retrieval and transplant considerations prior to NORS arrival at Donor hospital.



Within the Consent section of DonorPath

3.6. On occasion the Coroner/PF may require discussion with retrieving surgeon(s) with certain stipulations and requests in relation to the retrieval/removal operation. Specific requests may include photos, completion of witness statement under section 9 of the Criminal Justice Act 1967/MG11 Forms or pathology/police presence at retrieval. Forensic samples such as swabs or the impression of any bite marks should only be taken by someone trained in forensic sampling.

3.7. If Coroner/PF restrictions result in a change to organ retrieval procedure that may impact individual organs, restrict supporting material (such as blood, lymph and spleen) or there is an inability to inspect the chest/abdominal cavity then consider escalation to LN/OMT On Call as appropriate as donation may still be possible and ensure all receiving centres, including the National Referral Centre (NRC), are informed as per **SOP4938**.

3.8. In any event, the SN should instruct the retrieval surgeon that incisions for organ retrieval/removal must not encroach upon any endotracheal tube, site of neck surgery or any evidence of neck ligature indentation. This should not prevent the retrieval surgeon from being able to perform a thorough assessment of the chest cavity.

3.9. Ensure the final decision document is utilised during all professional handovers including the SN to SN, and SN to NORS team.

FULL LACK OF OBJECTION TO DONATION

3.10. If the Coroner/PF provides a **full lack of objection** to organ and/or tissue donation and removal of organs for other/scheduled purposes on the information presented, the SN must confirm any special requirements or specifications and document it clearly in the patient's medical records and on DonorPath or **FRM4039** in the event of system outage (**SOP3925**). All relevant stakeholders and the donor family must be informed.

3.11. If the Coroner/PF has provided full lack of objection for all requested organs and tissue but has placed restrictions on organs and tissues that have not been requested for donation (e.g. organs/tissue contraindicated as per **POL188** or deemed untransplantable) – this is a restricted (partial) objection to donation and must be documented as such in the donor record and PDA.

RESTRICTED (PARTIAL) OR FULL OBJECTION TO DONATION

3.12. If the Coroner/PF provides a **restricted (partial) objection** to any organs and tissue for donation, then the SN must explore further with the Coroner/PF and Pathologist if there are any implications for other organs being retrieved. i.e., if there is a strict request for the heart to be untouched then it is unlikely lung donation can proceed, as the lungs are unable to be removed without touching the heart.

3.13. If the Coroner/PF provides a **full objection** to organ and/or tissue donation, the SN should ascertain the reasons why donation cannot proceed.

3.14. If a forensic or hospital pathologist has not contributed to the judicial decision, the SN should advocate for expert input to ensure proper organ and tissue retrieval considerations. The SN should explore with the Coroner/PF office if any donation options may support a restricted lack of objection. For example:

a) Where possible or by regional agreement the SN should request to speak to the Coroner/PF directly to discuss the rationale behind the objection to donation.

b) Whilst full organ and/or tissue donation may not be permitted, restricted permission may be an acceptable compromise for the Coroner/PF.

c) Further discussions between Coroner/PF and lead clinicians about the patient's injuries and/or the cause of death may assist in full lack of objection or restricted objection being granted for donation; whilst the death might be unnatural, a cause could be clear.

d) It is beneficial to ensure all multi agency professionals are making decisions with the same understanding of the donation request and process. Therefore, it can be helpful for the SN to request a virtual meeting to include relevant members such as Coroner/PF Office, Police, Pathologist, Clinical team and possible NORS representation to discuss the decision. If this occurs the SN must take details notes of the decisions from the meeting and ensure this is documented in the donor record.

e) Attendance of Forensic and/or Home Office/Crown Office Pathologist healthcare professionals can allow for an accepted form of post-mortem to take place, if a possibility.

f) Completion of relevant evidential paperwork by the SN or retrieval surgeons (Section 9 Statements (Form MG11) - voluntary statements provided in compliance with the Criminal Justice Act (1967)) if required by the Coroner/Procurator Fiscal.

g) In attempt to preserve evidence (e.g. suspected murder case) it is very important to involve the Police. Discussions should be held between the SN, Coroner/PF office, Pathologist, and Police teams to consider this possibility. Any family keepsake requests should be discussed at this point.

3.15. In cases where donation is non-proceeding based on a final full objection decision, the SN must document this clearly in the patient's medical records and on DonorPath or **FRM4039** in the event of system outage (**SOP3925**) and any evidence of the decision is uploaded to DonorPath. The SN must inform all relevant stakeholders and donor family members of the Coroner/PF decision and document this.

DIGITAL PROFORMA

REQUIREMENTS FOR THE RECEIPT AND DOCUMENTATION OF FRM7248 CORONER REFERRAL PROFORMA

3.16. The Coroner/Coroner Officer will review and document the lack of objection, restriction or full objection decision on **FRM7248**, and return this to the SN as a locked and non-editable PDF copy.

3.17. The decision of the Coroner/Coroner Officer will be documented in various parts, as related to the decision. See below:

- Part Two if **Full Lack of Objection** from Coroner (section F if applicable information shared).
- Part Three, Four (Sections A-E) and Five if **Restricted (partial) Objection** decision (section F if applicable information shared).
- Part Five if **Full Objection decision** from the Coroner (section F if applicable information shared).

3.18. The final decision, by the Coroner, detailed in the completed **FRM7248** will be returned by the Coroner/Coroner Officer by email to the SN via the regional ODST NHSBT email address identified on the proforma.
N.B. If the Coroner/Coroner Officer wishes to contact the SN/Clinician by telephone to verbally relay the coroner's final decision, this can still occur but the return of completed **FRM7248** Proforma in locked PDF form is still required later if the Coroner can do so (likely when the Coroner is supporting donation out of hours). If a completed **FRM7248** cannot be returned for any reason, the SN must ensure thorough transcription of the decision is inputted into the donor record.

3.19. If all requests have been answered and documented on the **FRM7248**, without any omissions or changes in the request since initial contact, the completed PDF copy of **FRM7248** must be used as documentation of the judicial decision for organ and tissue donation.

3.20. The SN must upload the final and completed **FRM7248** to be available for any SN taking over the care of the donation case and the document must be referenced in each SN and NORS handover.

4. POST DONATION COMMUNICATION WITH CORONER / PROCURATOR FISCAL

4.1. Where lack of objection or restricted objection from Coroner/PF has been received, the SN should inform the Coroner/Procurator Fiscal if donation does not proceed. This should be agreed with the Coroner/PF in discussion or by observing local practice (usually updated by telephone or secure email). This could be due to no organs being accepted by recipient centres, an uncontrolled death during the donation process, family decline or reversal of consent/authorisation or prolonged time to asystole etc.

4.2. In proceeding donation, communication must take place with the Coroner/Procurator Fiscal following donation by the SN to confirm which organs and tissues have been retrieved in theatre. A pre agreed method with the Coroner/PF should be arranged at time of referral and the SN must document actions in sequence of events.

4.3. If a Coroner/PF has provided a full lack of objection or restricted partial objection for donation to proceed, and donor family also consented/authorised for donation to proceed – the SNs must document the Coroner/Procurator Fiscal name and email address in the 'Hospital Contacts' section on DonorPath. A member of the DFCS team will draft the letters and circulate using Coroner/Procurator Fiscal covering email to the involved SNs for review and dissemination (**MPD845**) and all actions documented and post donation action tracker updated.

4.4. This letter will be an edited version of the staff letters produced by DFCS as per **MPD845**, sent to any individual(s) or department(s) involved in the donation process. The Coroner/PF will not receive more information than that contained within the family letter and any embargoed novel transplantation will not be detailed.

4.5. Should the family not wish to receive follow up information then the Coroner/PF must not receive the information. The DFCS may write to the Coroner/PF with a limited outcome Health Care Professional letter to explain the reasons for this if requested by the SN.

4.6. Some Coroners/PFs may choose to read out this letter at the inquest describing the recipients, and to offer a public acknowledgement of thanks. It is the Coroner/PF responsibility to inform next of kin if they plan to disclose any information contained in this letter during the inquest.

4.7. In cases of multi-agency collaboration in donation with Police and Pathologists, the SN can include the specifically involved individuals as further recipients of the Coroner/PF outcome letter if deemed appropriate and necessary – to be securely emailed as per **MPD845**.

4.8. The Clinical Administration Team (CAT) will inform the coroner of which tissue has been retrieved post tissue retrieval from consented/authorised proceeding/non-proceeding organ donors when requesting the final/provisional cause of death as per **SOP6079**.

5. TISSUE ONLY DONATION – National Referral Centre and Clinical Administration Team Only

Deceased donor referrals for tissue donation to the National Referral Centre (NRC) occur from several sources which includes, hospitals wards, bereavement offices, hospices, families, care facilities and community healthcare professionals. In some cases, the circumstances surrounding the death of the patient would lead the medical teams who had provided treatment to the patient to contact the Coroner/PF.

5.1. On receipt of the referral for deceased donation the SNTD must enquire if the case is expected to be referred to the coroner and gather information from referring party around circumstances of death.


England & Wales

a) In England and Wales only, a discussion should occur with the hospital Medical Examiner (ME) to confirm if a death or expected death requires referral to HM Coroner. This is to ensure a lack of objection decision for tissue donation is sought from the HM Coroner in appropriate cases before retrieval. The SN will contact the ME and/or bereavement office during available hours to gain more information around circumstances of death and enquire if medical teams are making a referral to Coroner. SN must follow steps in Section 1 for this process. Details of trust/health board processes can be found in the NHSBT National Judicial Database, located in the Judicial Process SharePoint.

b) If the Coroner/PF Jurisdiction has agreed Blanket Lack of Objection for Eye Donation agreement in place, this will be specified on the NHSBT National Judicial Database. If the potential donor meets the criteria of the aligning Coroner/PF, the SN can progress the case of ocular only donors without notification to the ME or Coroner/PF.


England & Wales

c) The SN will assess against circumstances where death must be reported to the Coroner for England and Wales. Appendix 1.1.


Scotland

d) For Scotland the referring party or Doctor who has certified death will be able to inform of requirement for referral to Procurator Fiscal. Guidance to when deaths should be reported to Procurator Fiscal can be found in Appendix 1.2.


Northern Ireland

e) Requirements and guidance for when deaths should be reported to the Coroner service in Northern Ireland can be found in Appendix 1.3.

5.2. For cases involving Police the incident log number will need to be sourced by SN.

5.3. In the absence of information around referral to Coroner, out of hours or at weekends the SN will need to assess if they will need to contact the Coroner/PF to discuss the case. The SN can consider escalating to the OTDT Operational Manager On Call for advice.

a) On referral to Coroner/PF the SN must ensure that the key information is communicated to the Coroner/PF office for a lack of objection decision to be made. When discussing with the Coroner/PF, SNs should ensure they list each tissue they are requesting and to request inclusion of a blood sample if required.

b) In circumstances where a blood sample to support tissue donation is to be sourced from a laboratory the SN is required to ensure they request permission from Coroner/PF for this blood sample.

c) Due to the time sensitive nature of requirement to facilitate eye donation within 24 hours of death the SN will need to inform the Coroner/PF of time restrictions for a decision.

d) To facilitate tissue or organ donation it may be required to consider for the donor to be moved to the dedicated donation facility at NHSBT premises in Speke Liverpool or arrange transfer from one facility to another e.g., Hospice to funeral directors or hospital to hospital, if this is the case the SN must request permissions from the coroner to do so and document decision clearly with any specific instructions from the Coroner/PF.

e) The SN is required to provide their name and contact number/email for the NRC.

f) This information is then assessed by the Coroner/PF to determine if organ and/or tissue donation and removal of organs for other/scheduled purposes can proceed, without compromising any potential investigations. It is vital that the SN documents such communication accurately so that the meaning is clear.

5.4. The Coroner/PF decision must be clearly documented in the relevant TissuePath section and include detail of any special requirements or restrictions.

5.5. For Organ Donation referrals, the SN in NRC must review the ‘Coroner/PF’ section information available in DonorPath ahead of arranging tissue donation to proceed. All restrictions to donation should be noted and if required, the SN should contact the Organ Donation Services Team (ODST) via the alert system to discuss, clarify and confirm all Coroner/PF restrictions for specific tissues.

5.6. The SNTD must document the Coroner/PF decision on TissuePath within the relevant section for handover to the retrieval team. If the Coroner/PF provides a full lack of objection or restricted (partial) decision for tissue donation the SNTD must confirm any special requirements or specifications and clearly document on TissuePath.

5.7. In cases where donation is standing down based on a final full objection decision, the SNTD must document this clearly on TissuePath.

5.8. The Clinical Administration Team will inform the Coroner/PF of which tissues have been retrieved when sending a request for cause of death **FRM1014** and/or provisional cause of death **FRM6029,** documented in **SOP6079**.

6. SHARING INFORMATION & ENGAGEMENT WITH JUDICIAL SERVICES

USE OF FRM7248 CORONER REFERRAL PROFORMA AND ENGAGEMENT

6.1. Across the UK, Coroners and Procurator Fiscals use a range of independently developed proformas, often with inconsistent information requests, despite the donation process being nationally standardised. **FRM7248** has been created following a review of existing forms and in collaboration with the Deputy Chief Coroner's Office and Forensic Pathologists. It is now the NHSBT endorsed referral proforma, intended to replace current written communication agreements and promote consistent use among Coroners who are willing to participate in use.

6.2. The SN must utilise **DAT4440** to identify a Coroners decision to use **FRM7248** in their referral process and any specific request made by the Coroner Jurisdiction. **INF1685 c**an be shared with the Coroner/Coroner Officer for any support with the request.
Coroner/PF offices not listed on **DAT4440** have not agreed to use **FRM7248** and the associated process, and practice should reflect non-proforma based communication or regionally agreed practice.

6.3. Following expression of interest from a Coroner Jurisdiction to use or transfer use to **FRM7248** in communication between NHSBT and their office, the SN and/or Coroner's Office should contact JudicialRequests@nhsbt.nhs.uk with this request.
This will ensure processes are agreed and ensure participation is registered on **DAT4440**.

NHSBT NATIONAL JUDICIAL DATABASE

6.4. For observation across the United Kingdom, if any new contact information or updates are received from judicial services/ME on referral or process requirements between a SN and Coroner/Procurator Fiscal, the details must be added to the NHSBT National Judicial Database for access by all SNs. Updates for the database should be submitted to the regional ODST or departmental Judicial Working Group lead.

6.5. In England and Wales, or Northern Ireland, **FRM7249** - Local Coronial Agreement for Organ Donation Referral Process should be used to guide the SN to document required details. All fields should be populated by the SN to reflect local referral process agreement where able. All areas of detail on **FRM7249** should be addressed to ensure NHSBT are working collaboratively with Judicial Services. Details submitted on this form will not require storage, but the updated details must be reflected on the database.

6.6. Any high priority changes received from a Coroner/Procurator fiscal should be immediately communicated to local ODST, NRC and CAT colleagues by email, in advance of steps taken to update the database.

PROVIDING WITNESS STATEMENTS

Members of the UK multi agencies, such as a Coroner/PF or member of an investigating Police force, can request a witness statement under Section 9 of the Criminal Justice Act 1967 at the time of donation. This is usually referred to a 'Witness 9 Statement' and may be required from any member of the donation and retrieval team. If a witness statement is requested as part of a lack of objection from the Coroner/PF, these can be provided with the advice below:

6.7. Firstly, ensure the Coroner/PF is aware the retrieval/operation record will be available in the medical notes following retrieval and confirm if this will satisfy their information request.

6.8. Where possible, ask the requesting agency to provide a 'Witness 9 Statement' template to support completion. There is variance in composition across the UK, however this example (right) will cover the requirements.

6.9. The healthcare professional must print and sign their name next to "statement of" and following the declaration (two signatures).

6.10. The author must also sign, print and date at the end of each page to declare witnessing the statement.

6.11. The SN must photocopy the completed and signed statement and include the copy in the hospital medical notes.

6.12. The SN must upload the completed witness statement to DonorPath as a miscellaneous document, with an appropriate title.

6.13. Once uploaded to DonorPath, a copy of the Witness Statement must be emailed to the requesting agency via secure email.

WITNESS STATEMENT (Example)

Statement of: PRINT NAME IN CAPITALS AND SIGN
I confirm I am over the age of 18: YES
Occupation: STATE YOUR OCCUPATION

This statement (consisting of pages each signed by the author) is true to the best of my knowledge and belief and I make it knowing that, if it is tendered in evidence, I shall be liable to prosecution if I have wilfully stated anything which I know to be false or do not believe to be true.

Date of statement: DATE AND TIME
Authors Signature: SIGN AND PRINT

I am a…….…. currently employed by…….…I have been so employed for ……. My qualifications are…….…

On…**DAY, DATE, TIME** … at the request of… **FULL NAME**… I attended…**FULL NAME**…department at …**FULL NAME**... Hospital.

There, I was involved in the care of a **male / female** (delete as appropriate) named … **FULL NAME HOSPITAL NUMBER**... I witnessed this patient at the hospital above before and after their death (**DELETE OR INCLUDE BOTH BEFORE AND AFTER AS NECESSARY**)

STATEMENT ADVICE: Complete a factual account of the proceedings and circumstance. This could relate to donor care or retrieval surgery/findings etc.
Note: it may be acceptable to copy the retrieval operation record as the witness statement.

SIGN, PRINT AND DATE

6.14. The original witness statement must be returned with the donor file to DFCS.

6.15. If the requesting agency requires the original statement to be sent to them, the SN must plan with DFCS to have the original document mailed to the relevant Coroner/PF or Police force with clear instructions of who to address the witness statement for the attention of.

OTHER REQUESTS FOR STATEMENTS

6.16. Healthcare professionals involved in patient care may receive requests for various types of statements from multiple agencies. Additionally, donor and recipient hospitals may request statements through patient safety or clinical governance channels. For example, a Coroner/PF may request a 'Schedule 5 Statement' under the Coroners and Justice Act 2009. There are several types of statements or notices included within legal and administrative documents. A request under Schedule 5 of the Coroners and Justice Act 2009 involves requiring individuals to provide evidence or documents related to an inquest.

A senior Coroner/PF can issue a notice under Schedule 5, requiring a person to attend an inquest, give evidence, or produce relevant documents. The request will specify a deadline for submission of the statement or evidence and outline potential consequences for non-compliance, such as fines.

6.17. If any request is made from multi agencies or a donor / recipient hospital that is not identified as a witness 9 statement from the time of donation, the SN must escalate the request to their regional LN to make necessary enquiries with the OTDT Patient Safety Team.

PATIENT SAFETY AND GOVERNANCE

6.18. The SN must complete a report to the OTDT Patient Safety team for any medical examiner or judicial process which impacts negatively on the organ and/or tissue donation process, to support any required learning.

This **does not** apply to a judicial decision of restricted or full objection to donation.

Link: https://safe.nhsbt.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx

7. APPENDIX

EXTERNAL RESOURCES AND PUBLICATIONS

APPENDIX 1.1 - The Notification of Deaths Regulations (2019)
Applicable Regions: England and Wales
Publisher: Ministry of Justice
Website: https://www.legislation.gov.uk/uksi/2019/1112

APPENDIX 1.2 - Reporting deaths to the Procurator Fiscal (2015)
Applicable Regions: Scotland
Publisher: Crown Office & Procurator Fiscal Service
Website: https://www.copfs.gov.uk/publications/reporting-deaths/

APPENDIX 1.3 - Working with the Coroners Service for Northern Ireland (v3)
Applicable Regions: Northern Ireland
Publisher: Coroners Service for Northern Ireland
Website: https://www.nidirect.gov.uk/articles/coroners-post-mortems-and-inquests#toc-0

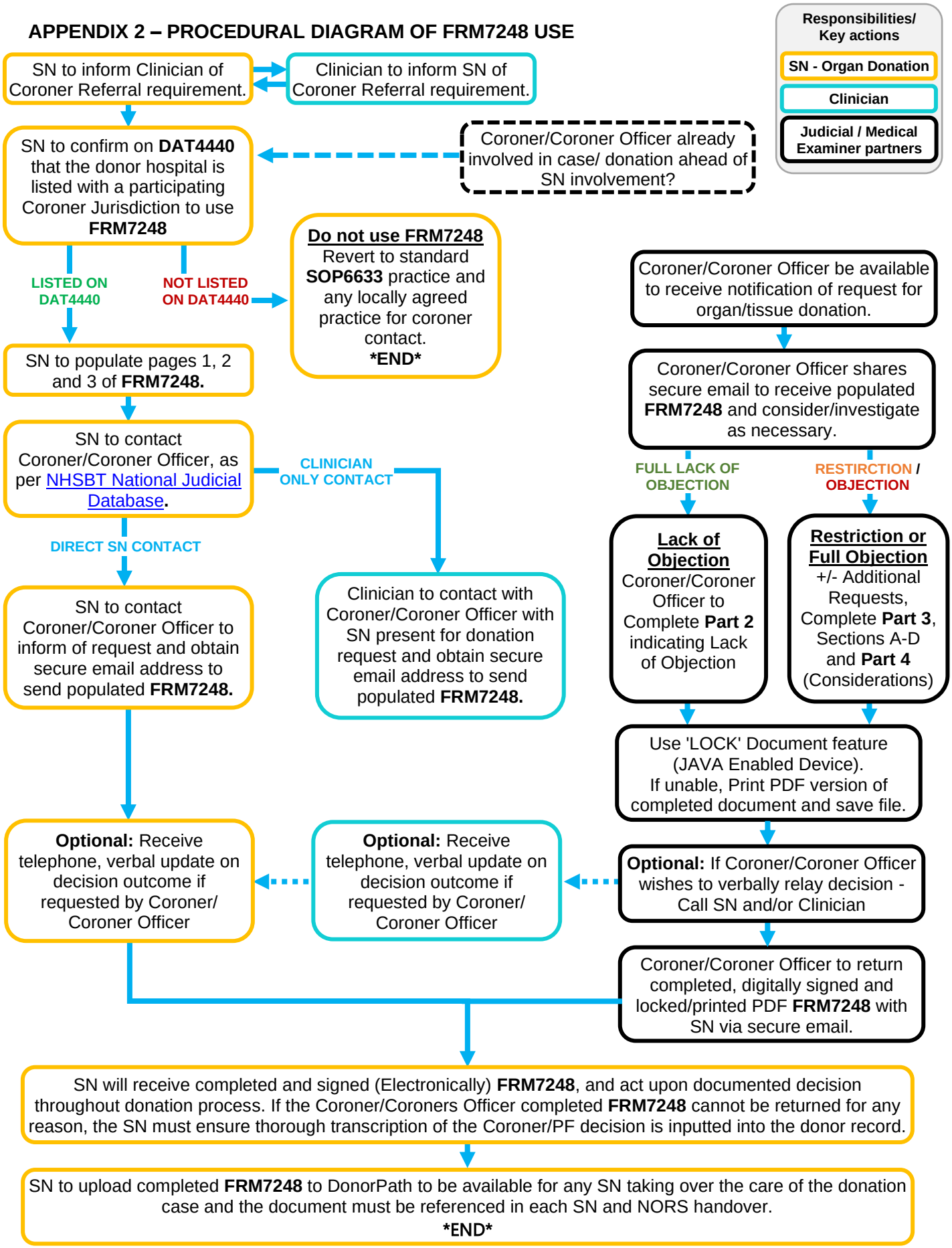
APPENDIX 1.4 - National Medical Examiner's Good Practice Series No. 4: Organ and Tissue Donation (2025)
Applicable Regions: England and Wales
Publisher: The Royal College of Pathologists
Website: https://www.rcpath.org/static/12d79507-48e1-4ae7-858615f0327da5c1/cbb8f4e5-aab1-492a-a10296c03d5fba2d/Good-Practice-Series-Organ-and-tissue-donation.pdf

APPENDIX 1.5 - Chief Coroner's Guidance No. 26 Organ and Tissue Donation (2017)
Applicable Regions: England and Wales
Publisher: The Coroners Society of England and Wales
Website: https://www.judiciary.uk/guidance-and-resources/chief-coroners-guidance-no-26-organ-donation/

APPENDIX 1.6 - Organ and Tissue Donation: Agreement between the Crown Office and Procurator Fiscal Service and the Scottish Donation and Transplant Group (2021)
Applicable Regions: Scotland
Publisher: The Scottish Government
Website: https://www.gov.scot/publications/agreement-between-crown-office-procurator-fiscal-service-scottish-donation-transplant-group-regard-organ-tissue-donation-2/

APPENDIX 1.7 - Major Crime Investigation Manual (MCIM 2021)
Applicable Regions: Nationwide
Publisher: National Police Chiefs Council
Website: https://library.college.police.uk/docs/NPCC/Major-Crime-Investigation-Manual-Nov-2021.pdf

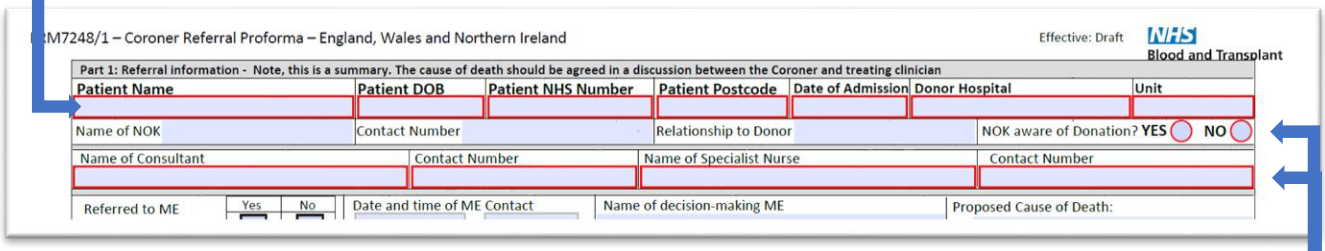
APPENDIX 2 – PROCEDURAL DIAGRAM OF FRM7248 USE



APPENDIX 3 - GUIDANCE FOR COMPLETING FRM7248 - CORONER REFERRAL PROFORMA – ENGLAND, WALES AND NORTHERN IRELAND

1. **Documenting:**
    a. **Patient Identifiable Data (PID)**
    b. **Next of Kin (NOK) details and SN/Clinician contact details.**

This section is mandatory - Populate the PID, admission date and donor hospital for the potential donor onto page one, which will then automatically populate on the PID heading of Page Two and Three (please always check this is visible on every page)



This section is mandatory - If known, document the Next of Kin (NOK) details in this section, and indicate with the 'YES/NO' option if the NOK are aware of potential donation request. Document the name and contact number of the Clinician in charge of the portential donors care, along with the SN name and contact number.

2. **Documenting:**
    a. **Medical Examiner/Coroner/Coroner Officer details and contact**
    b. **Proposed cause of death**
    c. **Blood sampling**

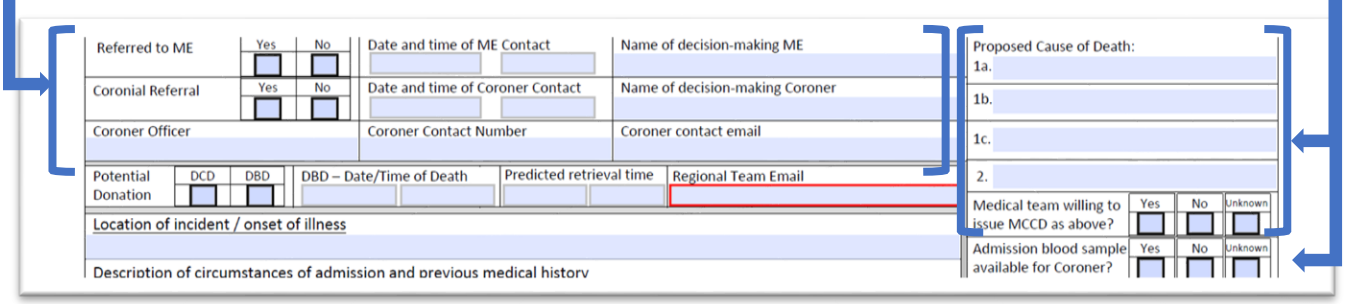
Where there has been discussion with a Medical Examiner (ME), detail the date and time of the referral/discussion and the name of the decision-making ME
Indicate 'Yes' for' Coroner Referral' and detail the name of the Coroner who is involved in this donation request, along with the Coroners Officer Name (if applicable) and the contact number of the Coroner and the GOV.uk or eJudiciary.net email address for the coroner contact.

The SN **MUST NOT** share **FRM7248** if a coroner's jurisdiction GOV.uk or eJudiciary.net email is not able to be used

If applicable, detail the clinicians proposed cause of death (transcribed from medical notes) and if the medical team are willing to issue this by using 'YES/NO/UNKNOWN' options.

Also, if known, indicate whether an admission blood sample is available for the coroner.
The SN **MUST** only select 'YES' if the request to hold the blood samples has been made and accepted by the laboratory team.

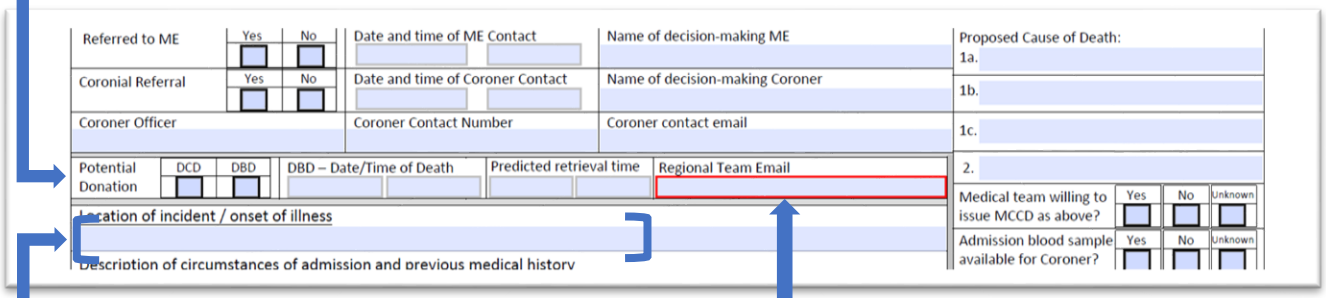
Page One 'Part 1'



3. **Documenting:**
    a. **Deceased donation details**
    b. **Location of incident/illness onset**
    c. **Email for return of decision.**

The SN must select the expected modality of deceased donation (DBD/DCD). If DBD, and the time of death has been confirmed, please detail this along with the predicted time of organ retrieval surgery.

Page One 'Part 1'



If known, the location where the incident or onset of illness occurred for the potential donor should be detailed.

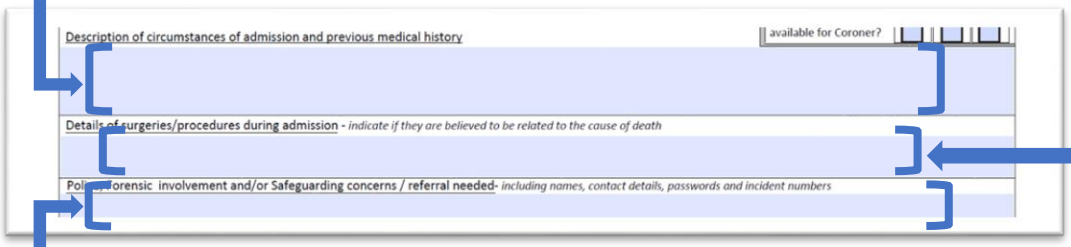
This section is mandatory - SN email contact should be the regional ODST NHSBT email address only and populated in the 'Regional Team Email' box. The return email will auto populate in Part 1 and 3 to support the coroner.

4. **Documenting:**
    a. **Circumstance of admission and past medical history**
    b. **Details of surgeries/procedures during admission**
    c. **Details of any police/forensic/safeguarding involvement**

The SN must clearly and accurately document a description of circumstances of admission and previous medical history.

Be mindful in this section, if transcribing from sections DonorPath to not include any data that is not of interest in description of circumstance (e.g. any DonorPath signposting or other irrelevant documentation).

Page One 'Part 1'



The SN must clearly and accurately document details of surgeries/procedures during this admission to inform the decision-making coroner.

N.B. The SN must ensure any details of these surgeries/ procedures that are believed to be related to the cause of death are highlighted.

The SN must clearly and accurately document details of Police, Forensic involvement and/or Safeguarding concerns and if a referral is needed or has been made.
N.B. Ensure details of any involved police/forensic/safeguarding personnel are listed with any established privacy passwords and police incident numbers.

5. **Documenting:**
    a. **Organ and tissue requests**
    b. **Free text organ, tissue and research requests**

Once the SN has completed all page one sections, the SN **MUST** populate through sections A-D on page two.

All selection boxes in the 'Requested' column aside each organ, tissue, research, novel, bespoke and intervention studies that are being requested must be indicated by checking each selection box.

Be clear in the free text boxes for:

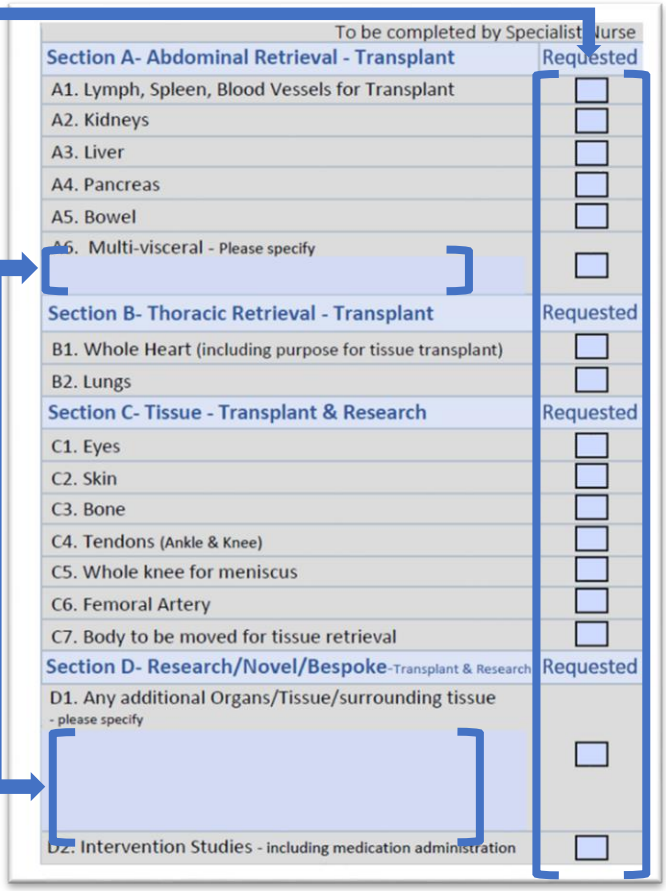
- Section A - (A6) 'Multi Visceral'
- Section D (D1) 'Research/Novel/Bespoke'

Clearly identify any organ and tissue requested and provide the name of any national and/or centre specific research studies identified.

No abbreviations should be used in these sections, to ensure clarity for the Coroner/Coroner Officer (e.g. 'QUOD' should be 'Quality in Organ Donation study')

N.B. Before completion, please take time to assess and confirm all necessary donation requests only for the potential donation case, aligning with **POL188** and any local donation centre transplant/research programmes.

Page Two
'Part 3'



To be completed by Specialist Nurse

Section A- Abdominal Retrieval - Transplant	Requested
A1. Lymph, Spleen, Blood Vessels for Transplant	☐
A2. Kidneys	☐
A3. Liver	☐
A4. Pancreas	☐
A5. Bowel	☐
A6. Multi-visceral - Please specify	☐
Section B- Thoracic Retrieval - Transplant	**Requested**
B1. Whole Heart (including purpose for tissue transplant)	☐
B2. Lungs	☐
Section C- Tissue - Transplant & Research	**Requested**
C1. Eyes	☐
C2. Skin	☐
C3. Bone	☐
C4. Tendons (Ankle & Knee)	☐
C5. Whole knee for meniscus	☐
C6. Femoral Artery	☐
C7. Body to be moved for tissue retrieval	☐
Section D- Research/Novel/Bespoke-Transplant & Research	**Requested**
D1. Any additional Organs/Tissue/surrounding tissue - please specify	☐
D2. Intervention Studies - including medication administration	☐

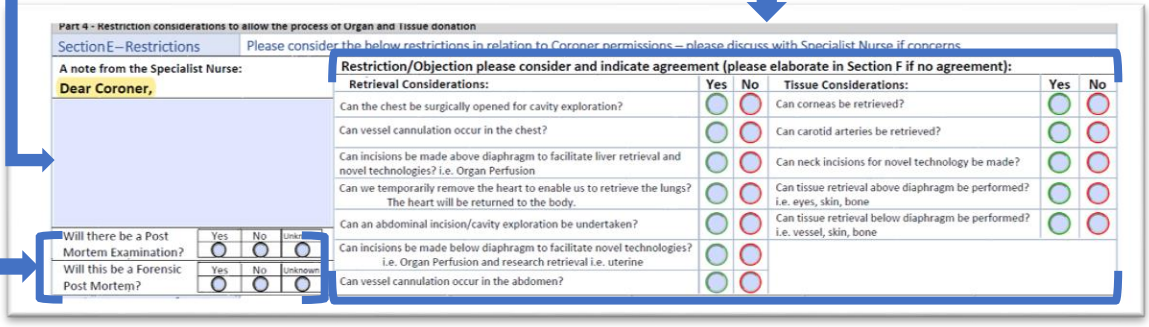
6. **Documenting 'Free Text' message for the coroner**

In Section E, within the 'Dear Coroner' free text box - the SN will complete a message to the Coroner/Coroner Officer of thanks for the donation request consideration, and any further extraordinary or pertinent requests that need highlighting.

The SN should prompt the Coroner/Coroner Officer in free text section E to consider the retrieval and tissue considerations. This helps gain clarity and reduces the need for further contact regarding restrictions, if they are in place.
This selection is for the Coroner/Coroner Officer to select, leave blank for submission to Coroner.

Page Three
'Part 4'

Leave the following boxes unselected (For Coroner/Coroner Officer to complete).



Part 4 - Restriction considerations to allow the process of Organ and Tissue donation

Section E – Restrictions — Please consider the below restrictions in relation to Coroner permissions – please discuss with Specialist Nurse if concerns

A note from the Specialist Nurse:
Dear Coroner,

Will there be a Post Mortem Examination?	Yes ☐	No ☐	Unknown ☐
Will this be a Forensic Post Mortem?	Yes ☐	No ☐	Unknown ☐

Restriction/Objection please consider and indicate agreement (please elaborate in Section F if no agreement):

Retrieval Considerations:	Yes	No	Tissue Considerations:	Yes	No
Can the chest be surgically opened for cavity exploration?	○	○	Can corneas be retrieved?	○	○
Can vessel cannulation occur in the chest?	○	○	Can carotid arteries be retrieved?	○	○
Can incisions be made above diaphragm to facilitate liver retrieval and novel technologies? i.e. Organ Perfusion	○	○	Can neck incisions for novel technology be made?	○	○
Can we temporarily remove the heart to enable us to retrieve the lungs? The heart will be returned to the body.	○	○	Can tissue retrieval above diaphragm be performed? i.e. eyes, skin, bone	○	○
Can an abdominal incision/cavity exploration be undertaken?	○	○	Can tissue retrieval below diaphragm be performed? i.e. vessel, skin, bone	○	○
Can incisions be made below diaphragm to facilitate novel technologies? i.e. Organ Perfusion and research retrieval i.e. uterine	○	○			
Can vessel cannulation occur in the abdomen?	○	○			