Objective

To describe the process for facilitating a forearm sentinel skin flap donation for use in multivisceral transplantation

Changes in this version

Point Revision: Alignment of retrieval/incisions description and language with SOP6496.

Roles

- **SN** – Specialist Nurse – Organ Donation / Specialist Requester: to identify multivisceral donor and consent/authorisation for multivisceral and skin flap donation.
- NORS team to facilitate organ donation.
- Oxford Recipient centre to co-ordinate forearm sentinel skin flap retrieval.
- Hub Operations to mobilise NORs retrieval team. If applicable, to offer sentinel skin flap to approved research studies.

Restrictions

- This SOP is to be followed by a qualified and trained SN/SR. In the event of a SN/SR who is in training, this SOP is to be utilised under supervision.
- Deemed consent does not cover consent for novel transplants, however consent/authorisation for organs and/or tissues for novel transplants, is still possible. This requires explicit consent from the family member in the Highest Qualifying Relationship (HQR).
- This process cannot be used with Donors after Circulatory Death (DCD)
- Consent for multivisceral and skin flap donation may occur nationally
- This SOP applies only to routine multivisceral and forearm skin flap donation for transplantation. **SOP6496** must be followed for the SENTINEL lungs and forearm skin flap clinical trial.

Instructions

Once the potential donor is identified as a potential Donation after Brainstem Death (DBD), and there are no identified absolute and organ specific contraindications (**POL188**), the SN may consider for forearm sentinel skin flap donation to support multivisceral transplantation.

Please note that if the patient is also a candidate for SENTINEL lung and skin flap study (**SOP6496**), consent may be taken for both but only on forearm skin flap will be retrieved. Should the donor proceed with both multivisceral and SENTINEL donation the forearm flap will be split in two by the attending plastic surgeon. If they are unable to do this, priority of the forearm skin flap will go to the multivisceral donation, and the SENTINEL study will be stood down. Lung donation will then continue as normal.

⚠ CAUTION

Deemed consent does not cover consent for novel transplants, however consent for organs and/or tissues for novel transplants, is still possible. This requires explicit consent/authorisation from the family member in the Highest Qualifying Relationship (HQR).

Process for forearm sentinel skin flap donation for use in **multivisceral transplantation (MV) ONLY**

SOP6496 must be followed for the SENTINEL lungs and forearm skin flap clinical trial.

Responsibilities/ Key actions

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

Potential DBD donor identified, with no identified absolute and organ specific contraindications for MV transplantation (**POL188**).

Approach donor family for multivisceral organ donation and observe any requirements in **SOP6039** – Abdominal Wall and Abdominal Fascia Transplantation

Family **provide consent / authorisation** for MV donation

Family **do not provide consent / authorisation** for MV donation

Approach for possibility of forearm skin flap donation to support MV transplantation

N.B. They do not have to consent to skin flap donation if they do not feel comfortable with this.

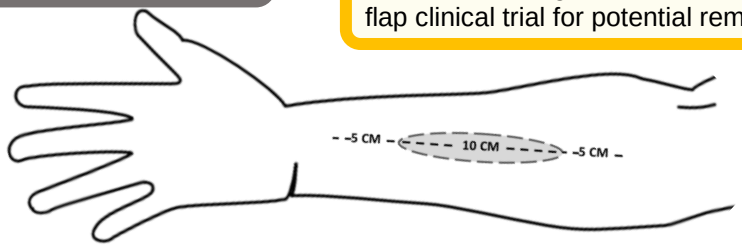
Family **do not consent / authorise** for forearm sentinel skin flap donation for use in MV transplantation.

STOP

Do not continue approach for forearm sentinel skin flap donation for use in MV transplantation

If applicable: follow **SOP6496** if SENTINEL lungs and forearm skin flap clinical trial for potential remains.

Family **do provide consent / authorisation** for forearm sentinel skin flap donation for use in MV transplantation

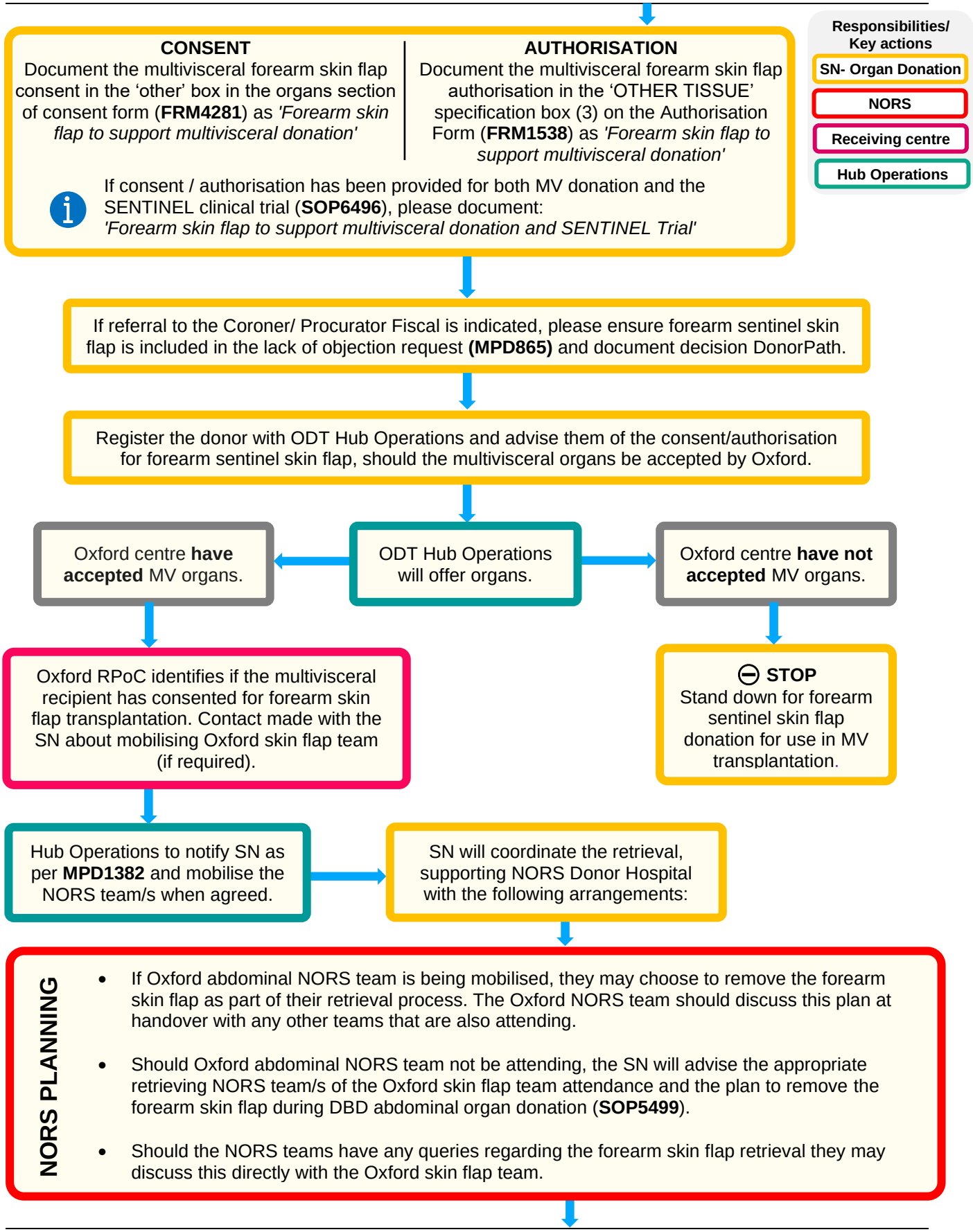


Complete consent/authorisation, ensuring the family are informed that the forearm skin flap donation is routinely taken to support the multivisceral organs as a method of monitoring rejection of the MV transplant.

Information to be given to family for skin flap donation:
The forearm skin flap size is approximately 10cm x 3cm and including the forearm skin and blood vessels. The skin flap may be taken from either the right or left forearm. In order to remove the skin flap and vessels, the incision will extend 5 – 10 cm lengthwise beyond each end of the skin flap. This means that the closure site and dressing will be longer than the skin flap that is removed. It is approximately a 20 cm straight line closure. The skin flap team will ensure a high standard of cosmetic closure, and it will have a dressing in place.

Forearm skin flap donation may not occur as this will only proceed if the multivisceral organs are accepted by one specific Recipient Centre.

If there is family consent/authorisation for tissues/organs to be used for scheduled/other purposes if removed and subsequently found to be untransplantable, the forearm skin flap will be offered out to approved research studies on the NHSBT research registry.


Responsibilities/ Key actions
SN- Organ Donation
NORS
Receiving centre
Hub Operations
CONSENT
Document the multivisceral forearm skin flap consent in the 'other' box in the organs section of consent form (FRM4281) as 'Forearm skin flap to support multivisceral donation'
AUTHORISATION
Document the multivisceral forearm skin flap authorisation in the 'OTHER TISSUE' specification box (3) on the Authorisation Form (FRM1538) as 'Forearm skin flap to support multivisceral donation'
If consent / authorisation has been provided for both MV donation and the SENTINEL clinical trial (SOP6496), please document:
'Forearm skin flap to support multivisceral donation and SENTINEL Trial'
If referral to the Coroner/ Procurator Fiscal is indicated, please ensure forearm sentinel skin flap is included in the lack of objection request (MPD865) and document decision DonorPath.
Register the donor with ODT Hub Operations and advise them of the consent/authorisation for forearm sentinel skin flap, should the multivisceral organs be accepted by Oxford.
Oxford centre have accepted MV organs.
ODT Hub Operations will offer organs.
Oxford centre have not accepted MV organs.
Oxford RPoC identifies if the multivisceral recipient has consented for forearm skin flap transplantation. Contact made with the SN about mobilising Oxford skin flap team (if required).
STOP
Stand down for forearm sentinel skin flap donation for use in MV transplantation.
Hub Operations to notify SN as per MPD1382 and mobilise the NORS team/s when agreed.
SN will coordinate the retrieval, supporting NORS Donor Hospital with the following arrangements:
NORS PLANNING
If Oxford abdominal NORS team is being mobilised, they may choose to remove the forearm skin flap as part of their retrieval process. The Oxford NORS team should discuss this plan at handover with any other teams that are also attending.
Should Oxford abdominal NORS team not be attending, the SN will advise the appropriate retrieving NORS team/s of the Oxford skin flap team attendance and the plan to remove the forearm skin flap during DBD abdominal organ donation (SOP5499).
Should the NORS teams have any queries regarding the forearm skin flap retrieval they may discuss this directly with the Oxford skin flap team.

Responsibilities/ Key actions

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

THEATRE PLANNING

- The donor needs to be positioned in theatre with their arm on an extension board to facilitate forearm skin flap donation.
- The forearm skin flap retrieval will be performed by Oxford NORS team or Oxford skin flap team and will take 30-45 minutes.
- The forearm skin flap closure will demonstrate a high standard of cosmetic closure and be dressed appropriately.
- Oxford NORS team are responsible for packing and packaging the skin flap when removed as additional tissue to support multivisceral donation.
- A copy of the corresponding HTA form will accompany the skin flap.
- The Oxford NORS team or skin flap team will document the retrieval in the hospital notes and complete a witness nine statement if required by the Coroner/Procurator Fiscal.
- The Recipient centre complete a HTA-B form if not transplanting the forearm skin flap.

RECEIVING CENTRE PLANNING

- The forearm skin flap will be transferred to Oxford, either with the Oxford NORS team, or if only the Oxford skin flap team have attended the forearm skin flap would travel with the other accepted organs to the Oxford Transplant Centre.
- Should the forearm skin flap be transferred to Oxford Recipient Centre and subsequently be deemed un-transplantable.
- The Recipient Centre will inform Hub Operations who will offer the skin flap for research if an approved study is available, or for disposal.

Hub Operations – for SN awareness

If there is family consent/authorisation for tissues/organs to be used for scheduled /other purposes if removed and subsequently found to be untransplantable, the forearm skin flap will be offered out to approved research studies on the NHSBT research registry.

Hub Operations will advise the accepting researcher of any family research consent/authorisation restrictions.

If the family decline for untransplantable tissue/organs to be offered for scheduled/other purposes, the forearm sentinel skin flap will be disposed of at the recipient centre.

SN to complete the SN to DFCS handover form including forearm skin flap donation in the tissues/organs donated – ‘other’ section (**FRM5499**).

If a multivisceral organ and forearm skin flap were donated, ensure the family are advised of this donation in the family letter, if they wish for this information (**SOP5818**).

End of Procedure

Definitions

- **DBD** – Donation after Brainstem death
- **DCD** – Donation after Circulatory Death
- **DFCS** – Donor Family Care Service
- **HTA** – Human Tissue Authority
- **MV** - Multivisceral transplantation
- **NORS** – National Organ Retrieval Service
- **RPoC** – Recipient centre Point of Contact
- **SN-OD** – Specialist nurse – Organ Donation
- **SR** - Specialist Requester

Related Documents / References

- **FRM1538** – Authorisation – Solid Organ and Tissue Donation
- **FRM4281** – Consent for Solid Organ and / or Tissue Donation
- **FRM5499** – SN to DFCS Handover Form
- **MPD1382** - Donation Pathway Communication Touchpoints – SN's, Hub Operations and RPoC's
- **MPD865** – Obtaining Coroner/Procurator Fiscal Decision
- **POL188** – Clinical Contraindications to Approaching Families for Possible Organ and Tissue Donation
- **SOP5499** – Theatre Manual for Deceased Organ Donors
- **SOP5818** – Organ and Tissue Donation Consent Manual
- **SOP6039** – Abdominal Wall and Abdominal Fascia Transplantation
- **SOP6496** – SENTINEL Trial

Training Plan for Documents:

Type of Change	Change to Existing Process>	
Stakeholders who require training	**Trainee new to the process**	**Trainee trained to the previous revision.**
	Specialist Nurses in Organ donation in all ODST Regions	Point Revision to v8.2 – awareness only to those trained to v8
Knowledge required prior to training	Full training through of SOP with PDS and Quality Lead	Point Revision to v8.2 – awareness only to those trained to v8
Critical aspects of process	To describe the process for facilitating a forearm sentinel skin flap donation for use in multivisceral transplantation >	

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.	Point Revision to v8.2 – awareness only to those trained to v8
Assessment	FRM511	Point Revision to v8.2 – awareness only to those trained to v8
Cascade Plan	Practical demonstration and read through the document with Regional ODST Quality Lead. Training material for this version will not cover the whole SOP content.	Point Revision to v8.2 – awareness only to those trained to v8 Author authorises self-directed training/update – specifically Scotland ODST

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	<2>

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

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

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	2	
Criticality of Change Score	1	1
Training Score	2	2

Recommended Training Method and Assessment:

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