

Objective

To support circumstances when there are ad-hoc tissue requests from a deceased solid organ donor for blood vessels or retrieval of rectus fascia.

This document will provide guidance on the key considerations ensuring safety and quality of the tissue to be retrieved for the benefit of the receiving patient.

Changes in this version

Update the process to enable use of Adobe request form and central storage point for requests.

Amendment to correct FRM details.

Clarity of language / responsibilities.

SNOD amended to SN

Addition of FRM6199 for ad-hoc vessels

INF1315 replaced with POL188

Roles

• Regional Manager

To ensure that all requests for ad-hoc blood vessels and rectus fascia are reviewed at the point of receiving the request maintaining the safety and quality of the tissue being transplanted.

• Specialist Nurse – SN

To ensure all blood vessels and rectus fascia from deceased donors are compliant with deceased tissue donor criteria set out in the JPAC guidelines unless in exceptional circumstances as outlined in this document.

To ensure that consent/authorisation is appropriately recorded and communicated ensuring traceability and that blood samples are collected and sent with the tissue to the transplant centre for mandatory testing required by the Human Tissue (Quality and Safety for Human application) Regulations 2007.

• Recipient Centre Points of Contact - RPOC

To ensure full details of the specific request are outlined utilising FRM6512. To ensure that where

tissue is accepted by a transplant centre in situations where tissue selection criteria have not been met that a risk assessment is undertaken and documented at the recipient centre.

• ODT Hub Operations

To ensure that any request for ad-hoc blood vessels and rectus fascia is dealt with using the process outlined maintaining the safety and quality of the tissue being transplanted. To ensure once agreed all requests are stored and visible to SNs and requests removed once fulfilled or expired.

• Donor Family Care Service

Include outcome in family communications as agreed.

• Information Services

For traceability purposes, review the HTA A and HTA B forms to ensure they include the removal of ad-hoc tissue.

Restrictions

• This process refers to ad-hoc requests for blood vessels and rectus fascia only. Any additional bespoke requests (such as trachea from a deceased donor) must be discussed with Quality Assurance - ODT who may feel it necessary to discuss the detail of any such specific request with the Human Tissue Authority. Any tissue procured must be listed on the Tissues Licence (HTA Licencing number 11018).

• Rectus fascia can only be retrieved by National Organ Retrieval Service Teams who have had their competence verified. Please refer to **INF1548** where these National Organ Retrieval Service Teams are listed.

Items Required

• JPAC
<http://www.transfusionguidelines.org.uk/dsg>

• **Appendix 1** - Ad-Hoc Tissue request process for RPOC, SN, HubOps and RM OnCall

Instructions

Advice

All users of this SOP must act in accordance with legislation frameworks in place across all territories of the United Kingdom where deemed consent/authorisation applies. Where ad-hoc rectus fascia or blood vessels are retrieved, express consent/authorisation is required.

1. Background

- 1.1 Requests for ad hoc blood vessels and rectus fascia are received by NHSBT ODT for patients that require emergency treatment following extensive surgery, organ transplants or occasionally in support of living donor transplants. Blood vessels and rectus fascia can be retrieved from a deceased organ donor to support these patients; such requests are supported by NHSBT on the basis of clinical need. In order to manage procurement of these ad-hoc grafts there are several points that must be considered to ensure mitigation of patient safety risks and ensure that NHSBT are compliant with the Human Tissue (Quality and Safety for Human application) Regulations 2007.
- 1.2 Tissue requests (specific for blood vessels or rectus fascia) may be made by a recipient Transplant centre. In all circumstances requests must be made in advance with appropriate consent/authorisation in place from the deceased organ donor. **Recipient centres are responsible for ensuring the timing of the request aligns with any planned date of surgery (as applicable).**
- 1.3 Tissue procurement may take place under NHSBT's Human Application Sector Licence (Tissues and Cells) – there is a Third-Party Agreement in place with NORS teams that permits this activity.
- 1.4 The centre receiving the tissue should have their own Human Application Sector Licence (Tissues and Cells) and the Designated Individual of this licence must agree to take responsibility for release of the tissue for clinical use and application of the tissue donor selection criteria (NHSBT will identify an appropriate tissue donor – the licensed centre must apply the tissue donor selection criteria and verify these are met).

2. Managing the Request

- 2.1 The requesting RPOC can make a request for ad-hoc blood vessels or rectus fascia using **FRM6512** available via <https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/procedural-documents/>. Contact can be made with Hub Operations if unable to access

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- FRM6512.** All sections of **FRM6512** must be fully completed including the specific tissue to seek consent / authorisation for.
- 2.2 On completion of **FRM6512** the RPOC should utilise the lock button which will automatically close all editable fields ensuring the request cannot be edited once sent. Utilising the email function send the form to Hub Operations via odthub.operations@nhsbt.nhs.uk
 - 2.3 Once submitted the RPOC should contact Hub Operations to confirm receipt on 0117 975 7580.
 - 2.4 On receipt, ODT Hub Operations should review the form labelling the pdf file clearly with patient nhs number and hospital. (E.g. nhs 1234567 Kings London .pdf).
 - 2.5 ODT Hub Operations should email a copy of the request to the Regional Manager on call shared email address organdonationrmon-call@nhsbt.nhs.uk and subsequently page the RM on call to request review.
 - 2.6 On receipt, the Regional Manager on call should review the details of the request for clarity dealing with any queries via ODT Hub Operations before confirming to ODT Hub Operations that they approve the request.
 - 2.7 Upon approval ODT Hub Operations must upload the pdf file to the nominated SharePoint Site '**TES Required Tissue Dashboard**' and store the pdf in the [Ad-hoc requests](#) designated folder.
 - 2.8 Should the request be deemed urgent and immediate the Regional Manager on call must email all SNs to advise the FRM has been added to the TES Required Tissue Dashboard site. On all other occasions the pdf should be added to the folder.
 - 2.9 It is the responsibility of ODT Hub Operations to remove **FRM6512** from the TES Required Tissue Dashboard when the request has been fulfilled or no longer required. A copy should be stored in F: Drive 'Other Tissue Request Forms' by Hub Operations for traceability purposes.

 **Caution**

Deceased donors must only be considered suitable to donate ad-hoc blood vessels or rectus fascia if they meet criteria for deceased tissue donation. The SN must refer to **POL188** and utilisation of <https://www.transfusionguidelines.org/dsg> as required. Further support and guidance on suitability for tissue donation can be provided by the National Referral Centre on 0800 432 0559.

There may be occasions when the recipient's surgical team are prepared to accept tissue from a donor that is contraindicated to donate tissue. In these circumstances, considerations of risk / benefit will be documented by the recipient centre. The SN should document on DonorPath that the relevant information has been passed on to the recipient centres. All discussions should be voice recorded as per **SOP3649**.

3. Obtaining Consent / Authorisation

- 3.1 On all occasions prior to obtaining consent/authorisation the SN should review the [Ad-Hoc folder](#) in the **TES Tissue Requirements Dashboard** SharePoint site for any such requests.
- 3.2 The SN should, if required, discuss any donors that fit the criteria outlined in **FRM6512** with the identified contact noted on **FRM6512**.

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- 3.3 Donor families will need to provide consent/authorisation for procurement of ad-hoc tissue/s for transplantation.
 - 3.4 Consent for removal of ad-hoc blood vessel/s or rectus fascia must be documented on the Consent (**FRM4281**) / Authorisation (**FRM1538**) and noted on Donor Path.
 - 3.5 Consent / authorisation must be clearly documented as 'other**', please specify'. The entry must include the specific tissue details **exactly as the request is noted on FRM6512** e.g. Rectus fascia.
 - 3.6 The removal of rectus fascia will not involve removing the abdominal skin just the muscles beneath the skin therefore families should be advised of this (this is different to abdominal wall where there will be no umbilicus).

4. Donor Registration and Offering

- 4.1 **It is the responsibility of the SN** to advise ODT Hub Operations that a suitable donor has been identified and that appropriate consent/authorisation is in place.

5. Blood Sampling

- 5.1 A blood sample will need to accompany the tissue so that donor microbiology can be carried out in an HTA licensed laboratory. This is a requirement of the Tissue and Cells Regulations. The volume and type of sample required should be specified in **FRM6512**, as per **SOP5499**.
- 5.2 It is the responsibility of the **SN** to ensure that a sample accompanies the tissue as per **SOP5499**.
- 5.3 It is the responsibility of the Transplant Centre to ensure testing is carried out in accordance with the Tissue and Cells Regulations and consider the subsequent results.

6. Packaging

6.1 For ad-hoc Blood Vessels:

- Any specific requirements should be confirmed on **FRM6512** by the Transplant Centre **at point of request**.
- The NORS retrieval team must be notified by Hub Operations in advance of departure and advise of any additional transport boxes required.
- The NORS team lead surgeon will ensure appropriate consent/authorisation has been documented during SN to NORS handover.
- **FRM6199** must be used to accompany any ad-hoc blood vessel requests
- A signed and witnessed copy of the blood group should accompany the ad-hoc vessels
- A copy of the HTA-A form must accompany the ad-hoc vessels – see section 7

6.2 For ad-hoc Rectus Fascia:

- Any specific requirements should be confirmed on **FRM6512** by the Transplant Centre **at point of request**.

- The NORS retrieval team must be notified by Hub Operations in advance of departure and advise of any additional transport boxes or equipment are required.
- The NORS team lead surgeon will ensure appropriate consent/authorisation has been documented during SN to NORS handover.
- A signed and witnessed copy of the blood group should accompany the ad-hoc rectus fascia.
- A copy of the HTA-A form must accompany the ad-hoc rectus fascia – see section 7.

7. Traceability

- 7.1 Robust traceability from donor to recipient is a regulatory requirement and is needed for family follow-up purposes. The SN must clearly document on **FRM5499** the tissue retrieved.
- 7.2 The specific tissue procured must be documented by the NORS lead or deputy where this has been delegated on an HTA A form (the kidney HTA-A **FRM4121** should be used if a kidney has been retrieved).
- 7.3 In circumstances where no kidneys are removed, liver / cardiothoracic HTA A form must be completed and returned to NHSBT.
- 7.4 The recipient centre should complete a HTA B form (**FRM4195**) and return to NHSBT with recipient details.
- 7.5 ODT Hub Operations must be made aware of the tissue procurement by the SN at the end of the donation process so that this can be captured in NTxD as per **SOP3839**.
- 7.6 ODT Hub Operations must make Information Services aware to alert them to the removal of ad hoc tissue as recorded on the HTA A and HTA B Forms.

8. Donor Records

- 8.1 SNs must ensure that **FRM5499** is completed advising DFCS of the retrieval of any ad-hoc tissue.
- 8.2 DFCS to cross reference against the donor Organ Outcome summary. This will ensure accurate outcome information is communicated to the donor family. Any discrepancy should be reported via the Clinical Governance Incident Reporting tool
<https://safe.nhsbt.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx>.

 **End of Procedure**

SOP5685/2 – Ad-hoc Tissue Requests of Blood Vessels and Rectus Fascia from Deceased Organ Donors



Blood and Transplant
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Definitions

- **Rectus Fascia** – a non-vascularised graft retrieved to support transplantation – closing abdomen / support of hernia repair post-transplant. The Human Tissue Authority classify Rectus Fascia as a tissue not an organ and therefore application of The Human Tissue (Quality and Safety for Human application) Regulations 2007 apply.

Related Documents/References

- **SOP3839** - Donor and Recipient Follow-up and Close Down
- **SOP5499** – Theatre Manual for Deceased Organ Donors
- **SOP3649** - Voice Recording of Organ Donor Clinical Conversations
- **INF1548** - NORS Retrieval of Rectus Fascia
- **FRM6512** - Ad-hoc Tissues Request Form
- **FRM6199** – [Vessel Form](#)
- **FRM4281** - Consent for Organ and/or Tissue Donation
- **FRM1538** - Authorisation – Solid Organ and Tissue Donation
- **FRM4121** - HTA A - Kidney Form
- **FRM4195** - HTA B Form
- **FRM5499** - SNOD to DRD Handover Form
- **POL188** – Clinical Contraindications to approaching Families for Possible Organ & Tissue Donation
- The Human Tissue (Quality and Safety for Human application) Regulations 2007
- **JPAC** - <http://www.transfusionguidelines.org.uk/dsg>

Appendices

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