



# **Lung Assessment and Recovery Centre (ARC) – Pilot Manual**

## **Donor Hospital to Lung ARC SOP 6838**

**Caring Expert Quality**

## ***Index***

---

**1. Summary of changes**

---

**2. Useful Information**

---

**3. Glossary**

---

**4. Potential Donor Referral, Consent/ Authorisation and Assessment**

---

**5. Donor Lungs EVLP at ARC Eligibility and Exclusion Criteria**

---

**6. Organ Offering**

---

**7. NORS Mobilisation**

---

**8. Retrieval**

---

**9. Arrival of Donor Lungs at Lung ARC**

---

## **1. Summary of changes**

New document

## **2. Useful Information**

---

***Background to Ex-vivo lung perfusion (EVLP)***

***Functions of Ex-vivo lung perfusion (EVLP)***

***Lung Assessment and Recovery Centre Pilot***

### **2.1 Background to Ex-vivo lung perfusion (EVLP)**

EVLP of donor lungs is now established as a safe and effective approach to assess the suitability of some potential donor lungs for clinical transplantation.

Donor lungs which have certain extended selection criteria or are deemed too marginal for direct transplantation may have the potential to be used successfully after a period of more detailed objective assessment and recovery during EVLP.

Successful EVLP requires careful evaluation of donor lung eligibility for EVLP, a skilled and trained multidisciplinary team to carry out EVLP and clear objective decision making on which organs achieve success criteria for transplantation after EVLP.

Collective decision making by the lung transplant multi-disciplinary team and collective responsibility for decisions made is an important part of a successful EVLP programme

Patients on the lung transplant waiting list should be informed and consented about the potential for EVLP use in assessing a donor organ that they may receive.

### **2.2 Functions of Ex-vivo lung perfusion (EVLP)**

EVLP can assist with increasing donor organ utilisation and improve access to lung transplantation for patients on the active lung transplant waiting list. There are 4 main functions of EVLP

- Provide an objective assessment of donor lung function to ensure organs are suitable for transplant
- Provide an opportunity to intervene to optimise donor lung function and re-assess suitability
- To extend preservation of the donor lungs outside the body and reset the ischaemic time
- To administer therapeutics to donor lungs that may be prophylactic or personalised treatments

### **2.3 Lung Assessment and Recovery Centre Pilot**

Aims of the Lung ARC pilot

- Test feasibility and safety of providing a national EVLP service to support increased donor lung utilisation
- To establish the logistics and governance arrangements for this new organ journey pathway
- To generate mechanisms for robust audit and data collection to be able to monitor ARC performance and impact
- To create a sense of national ownership of the ARC EVLP programme as a service provided by some for the benefit of all

### **3 Glossary**

<b>Role</b>	<b>Responsibility in ARC pathway</b>
Recipient Centre Point of Contact (RCPoC) - Accepting Transplant Centre	Recipient Centre Point of Contact – Accepting Transplant Centre communicates between HUB, SN and Lung ARC to coordinate acceptance and transport of donated lungs
Recipient Centre Point of Contact – ARC (RCPoC ARC)	Mobilises EVLP team and continues to support communication between Lung ARC Clinical Lead/Lung ARC EVLP Operator/RCPoC Accepting Centre and Accepting Transplant Surgeon
Accepting Transplant Centre	Accepting Transplant Centre that have accepted donor lungs for a recipient. Will need to maintain communications between Hub, donor hospital, ARC centre to support transplant pathway.
Accepting Transplant Surgeon	Lung Transplant Surgeon makes decision to accept lungs for transplant for a recipient. Will request Lung ARC if EVLP inclusion criteria met. Will agree this with Lung ARC lead Surgeon
Lung Assessment and Recovery Centre (ARC)	Specialist centre who will undertake Ex-Vivo Lung Perfusion (EVLP) of donor lungs on behalf of the Accepting Transplant Centre
Lung ARC Lead Surgeon	Leads the EVLP team at the Lung ARC. Supervises the EVLP team, liaises with Accepting Transplant Surgeon to support decision to accept for EVLP and then transplant. Undertakes or oversees the assessment of donor lungs pre-EVLP, cannulation of lungs and placing on EVLP circuit.
EVLP Operator Lung ARC	Perfusionist to set up and prime EVLP circuit, initiate perfusion and monitor perfusion indices and lung physiology
Hub Operations	Hub Operations provides a link in the transplant process between the Organ Donation Services Teams, the National Organ Retrieval Service, and transplant centres. Hub Operations supports the organ donation and transplantation community by matching organ donors to potential recipients
Specialist Nurse (SN)	Nurse who supports potential donor families and the operational processes of organ donation.
Ex-vivo Lung Perfusion (EVLP)	A medical technique that keeps donor lungs functioning outside the body to assess and improve their quality before transplantation. This technique can make marginal lungs suitable for transplant.

## **4 Potential Donor Referral, Consent/ Authorisation and Assessment**

---

### **4.1 Potential Donor Referral, Consent/ Authorisation and Assessment**

SN to follow processes for referral, approach, consent/authorisation and characterisation as outlined in:

- SOP3781 – Receipt of Referral of a Potential Organ and/or Tissue Donor
- SOP6589 - Advanced Multi Organ Screening (AMOS)
- SOP5818 – Organ and Tissue Donation Consent Manual
- SOP6405 – Donor Characterisation Manual
- SOP5878 – Organ and Tissue Donation Authorisation Manual

There are no new or additional requirements through these processes

## **5 Donor Lungs EVLP at ARC Exclusion and Eligibility Criteria**

---

**Donor Lungs EVLP at Lung ARC Exclusion Criteria**

**Donor Lungs EVLP at Lung ARC Eligibility Criteria at offering/acceptance**

**Donor Lungs EVLP Exclusion Criteria – Findings during retrieval**

ARC Eligibility and Exclusion criteria are applied by Accepting Transplant Centre and Lung ARC at time of offering (not including fast track)

### **5.1 Exclusion Criteria donor lungs EVLP at Lung ARC**

- Absolute contraindication and lung specific contraindication as per POL188 Clinical Contraindications to Approaching Families for Possible Organ & Tissue Donation
- Traumatic injury to donor lungs for example contusions and/or lacerations
- Donor weight below 35kg and/or height 1.4m and under
- Location of Donor Centre - Lung ARC - Accepting Transplant Centre (not eligible for flight travel)
  - Donor Centre - Lung ARC travel >6 hours
  - Lung ARC - Accepting Transplant Centre travel >5 hours

### **5.2 Eligibility Criteria donor lungs EVLP at Lung ARC at the time of offering /acceptance**

To be considered for EVLP the donor lungs must satisfy one or more of the following eligibility criteria

#### **Donor History**

- Possible donor Pulmonary Embolism
- Multiple blood transfusions
- Smoking history >20 pack years with borderline systemic arterial blood gases

#### **Donor Lung Function**

- Systemic PaO<sub>2</sub> < 40 kPa on 100% FiO<sub>2</sub> & 8cm H<sub>2</sub>O PEEP
- Sustained peak airway pressure > 30cm H<sub>2</sub>O on target tidal volumes
- Deteriorating systemic PaO<sub>2</sub> over time

#### **Donor Lung Imaging**

Chest x-ray (CXR) or Chest Computed Tomography (CT) findings prohibitive to standard transplantation such as:

- Significant atelectasis
- Generalised oedema
- Focal 'radiological' consolidation

- Infiltrates of unclear cause

Bronchoscopy findings (if available)

- Inflammation or soiling of the airway at bronchoscopy
- Recurrent but not prohibitive secretions in the distal airway after adequate bronchial toilet

### **5.3 Findings during retrieval**

See Section 8.3

### **5.4 Request for ARC EVLP during Retrieval**

Request and agreement for lungs to go to Lung ARC can only be agreed at offering and acceptance pre retrieval.

If on inspection in theatre it is felt that the lungs would benefit from EVLP but not placed with an ARC already then EVLP can be performed by the Accepting Transplant Centre if they have this expertise.

Request for Lung ARC assessment being made from retrieval will not be supported in the pilot phase.

## **6 Organ Offering**

---

**Lung ARC availability**

**Donor Lung Distribution and Allocation**

**Donor Lungs accepted on offering and referred to Lung ARC for EVLP assessment**

**Donor Lungs accepted for EVLP by Lung ARC**

**Donor Lungs not accepted for EVLP by Lung ARC**

### **6.1 Lung ARC availability**

Lung ARC to provide Hub operations with planned rota identifying weeks when available for ARC. Lung ARC to communicate to Hub by telephone to confirm ARC available at the commencement of the rostered period and again to confirm closed at the end of roster period.

Lung ARC MUST inform Hub Operations if ARC becomes unexpectedly unavailable e.g. staffing issues/machine malfunction

### **6.2 Donor Lung Offering and Allocation**

Hub Operations undertake donor lung offering and allocation as per Donor Lung Distribution and Allocation Policy (POL230) and ARC Lung Offering Process (SOP6837)

Refer to DAT4955 for visual representation of ARC lung offering and allocation processes.

### **6.3 Donor Lungs accepted on offering and referred to Lung ARC for EVLP assessment.**

RCPoC Accepting Transplant Centre must confirm with Hub operations the location of Lung ARC and that they are available to provide ARC EVLP. Accepting Transplant Centre has responsibility to review EVLP eligibility criteria is met (Section 5) and ensure that no exclusions are identified before a decision is made to accept lungs via ARC.

Offering will continue as per SOP6837. Centres can respond to offer with 3 outcomes

- Accept direct to transplant
- Accept via Lung ARC
- Decline

Lungs will be allocated for direct transplant first. If there is no acceptance for direct transplant, then the Hub will allocate the lungs to the centre at top of the offering sequence who has expressed an interest to accept via ARC. If a centre that has expressed an interest in accepting lungs via the ARC does not receive a call back from Hub confirming allocation, then this means lungs have been allocated elsewhere in line with POL230 and SOP6837.

It is the Accepting Transplant Centre responsibility to ensure adequate consent is in place for their recipient to receive lungs that have received machine perfusion.

Once Hub confirm offer with Accepting Transplant Centre then Accepting Transplant Centre RCPoC MUST contact Lung ARC immediately to discuss potential for Lung ARC EVLP.

<b>Lung ARC</b>	<b>Lung ARC contact information</b>	<b>Ask for</b>
Royal Papworth Hospital	01223 638 000	Lung transplant coordinator

There will then be an additional 45-minute post offer acceptance for the Accepting Transplant Centre and Lung ARC to make final decision about acceptance of organ via ARC. The aim of this conversation is to reach a clinical consensus on the suitability of the lungs for EVLP at Lung ARC. In the event of disagreement then the ARC Surgeon has the responsibility to make final decision about acceptance to Lung ARC.

#### **6.4 Donor Lungs accepted for EVLP by Lung ARC**

Accepting Transplant Centre RCPoC to advise Hubs Ops and SN that Donor Lungs accepted and will be going via Lung ARC.

#### **6.5 Donor Lungs not accepted for EVLP by Lung ARC**

Accepting Transplant Centre RCPoC to notify Hub Operations if donor lung offer declined following discussion with Lung ARC. Hub to continue offering as per POL230 and SOP6837.

If Lung ARC decline EVLP because the lungs do not meet the eligibility criteria for EVLP, then subsequent centres cannot request the use of the ARC.

The Accepting Transplant Centre must communicate the reason(s) for decline to Hub Operations.

## **7. NORS Mobilisation**

---

### ***Logistics and NORS Mobilisation***

***Lung Retrieval – Information to be communicated to allocated Cardiothoracic NORS team***

#### **7.1 Logistics and NORS Mobilisation**

Logistics & NORS Mobilisation Manual - Hub Operations SOP4574 will be followed to allocate a Cardiothoracic NORS team to attend and retrieve donor lungs.

Once a departure and arrival time has been agreed with the Cardiothoracic NORS Team, this will be communicated to the SN by Hub Operations.

SN to advise the Accepting Transplant Centre RCPoC who the allocated Cardiothoracic NORS Team is and the planned arrival time at the donor hospital.

The Accepting Transplant Centre RCPoC has the responsibility to arrange transport of donor lungs from the donor hospital to the Lung ARC.

The Accepting Transplant Centre RCPoC must contact the allocated Cardiothoracic NORS team lead surgeon and advise that the donor lungs have been accepted for EVLP at the Lung ARC and discuss the retrieval.

The Accepting Transplant Centre RCPoC must keep the Lung ARC EVLP Operator updated with proposed timings for theatre and estimated time for lungs to be transported to ARC. The Lung ARC EVLP Operator can be contacted via the RCPoC at the transplant centre in which the Lung ARC is located.

#### **7.2 Lungs should be assessed and retrieved according to the National Standards for Organ Retrieval from Deceased Donors (MPD1043). The following additional requirements must be communicated to the lead Cardiothoracic NORS surgeon, pre retrieval by the Accepting Transplant Centre RCPoC.**

- As long a trachea as possible should be retrieved to facilitate intubation of the lungs during EVLP
- If donor heart is not retrieved, the whole length of pulmonary artery and as big cuff of left atrial cuff as possible should be retrieved.
- Under no circumstances should pulmonary artery be divided into left and right branches and as large a left atrial cuff as possible should be provided.
- If the donor heart is retrieved for valves (requiring a generous portion of pulmonary artery to accompany the donor heart to the heart valve bank) then the Cardiothoracic NORS team should provide ~ 10 cm of descending aorta alongside the lungs to elongate any short main pulmonary artery.

- If heart is retrieved for transplant the same principles regarding the pulmonary artery as for the heart for valves should be used. The left atrial cuff should be big enough to allow the left atrial EVLP cannula to be stitched on.
- A large amount of donor pericardium and 10cm of thoracic aorta should be sent with the lungs.

## **8. Retrieval**

---

**Communication - SN and Accepting Transplant Centre RCPoC during retrieval**

**Communication - Accepting Transplant Centre RCPoC and Lung ARC during retrieval**

**Findings during retrieval**

**In Theatre Support, Collection, Labelling and Transport (Organ Samples)/ Organ Packing**

**SENTINEL Trial**

### **8.1 Communication between SN and Accepting Transplant Centre RCPoC during retrieval**

As per the Theatre Manual for Deceased Organ Donors SOP5499, the SN communicates with the Accepting Transplant Centre RCPoC during retrieval. There is no requirement for SN to communicate with the Lung ARC unless there are findings during retrieval that require multiway communication.

As part of organising the retrieval, clarification and agreement must be sought by the SN with the Accepting Transplant Centre RCPoC regarding the following, and must be clearly documented on DonorPath:

- Mode of communication - telephone number/email address.
- Time points of communication which are required for the retrieval.
- If using DonorPath / TransplantPath, ensure key touchpoints are agreed as TransplantPath will not alert RCPoCs.

The SN must take into consideration the requests of the Accepting Transplant Centre RCPoC and communicate these with the NORS Team. Such requests may include:

- Photographs capturing the consolidation in the donor lungs.
- Video of the 'deflation test'

All organ media (images and videos) should be taken via the DonorPath app. The actions taken need to be documented within DonorPath as per Guidance and Principles – Donor Related Files, Images and Video MPD1100.

### **8.2 Communication - Accepting Transplant Centre RCPoC and Lung ARC during retrieval**

The Accepting Transplant Centre RCPoC communicates with Lung ARC during retrieval.

As part of organising the retrieval, clarification and agreement must be sought regarding the following with the Lung ARC by the Accepting Transplant Centre RCPoC.

- Mode of communication - telephone number/email address.
- Time points of communication which are required for the retrieval.

### **8.3 Findings during retrieval**

#### **8.3.1 On inspection lungs appear better than expected and are suitable for direct transplant**

If on inspection the lungs appear better than anticipated, the lead Cardiothoracic NORs surgeon and Accepting Transplant Centre must have a conversation and agree if lungs are to be sent directly to the Accepting Transplant Centre for direct transplant. Intended recipient remains the same and no requirement for additional offering. The Accepting Transplant Centre RCPoC must inform SN, Hub Operations and Lung ARC if this occurs.

#### **8.3.2 Lungs deemed suitable for EVLP on inspection and assessment**

- Donor lungs to be sent to Lung ARC for EVLP.
- Accepting Transplant Centre RCPoC to notify Lung ARC and Hub Operations.

#### **8.3.3 EVLP Exclusion Criteria at retrieval include:**

- Traumatic injury to donor lungs – contusions, lacerations etc
- Established frank consolidation due to pneumonia
- Failed deflation test and/or visible bullae/high suspicion of emphysema

If any of the above are identified during retrieval, then the donor lungs are not to be sent to Lung ARC for EVLP. The Accepting Transplant Centre RCPoC must notify the Lung ARC and Hub Operations.

#### **8.3.4 Findings at retrieval requiring discussion**

It is important that there is good communication between the Cardiothoracic NORs team, the Accepting Transplant Centre and the Lung ARC throughout the retrieval.

If any of the below are found at retrieval this must trigger a multi-way conversation between the lead Cardiothoracic NORs surgeon, the Accepting Transplant Centre surgeon and the Lung ARC lead surgeon to agree how best to proceed.

#### **Donor Lung Inspection and function**

- Failed lung deflation test in absence of visible bullae/emphysema
- Persistent atelectasis despite active recruitment manoeuvres
- Inflammation or soiling of the airway at Bronchoscopy
- Recurrent but not prohibitive secretions in the distal airway after adequate bronchial toilet
- Unsatisfactory palpation of the lungs (undetermined masses, nodules or oedema)
- Unsatisfactory inspection of lungs after procurement and administration of second retrograde preservation flush
- Selective Peripheral Vein gas  $pO_2 < 30$  kPa on 100%  $FiO_2$  & 8cm  $H_2O$  PEEP

#### **Donor after Circulatory Death**

- Functional Warm Ischaemic Time (FWIT\*) > 60 minutes but < 120 minutes
- Undergoing abdominal Normothermic Regional Perfusion (aNRP) with any additional concerns about lung flush or function

\*FWIT defined as time from Systolic BP <50mmHg and/or systemic saturations below 70%

**Note**

Consider removal of lungs for full assessment on the back bench if there is doubt about their eligibility for Lung ARC EVLP.

A multi-way conversation should be arranged by SN. Consider use of Teams/telecom. This conversation at a minimum must include:

- NORS Cardiothoracic Retrieval team lead
- Lung ARC Clinical Lead
- Accepting Transplant Surgeon
- SN facilitating the retrieval
- Accepting Transplant Centre RCPoC

If logistics do not allow a telecom/ MS Teams call to take place, the following communication pathway must be followed.

- NORS Cardiothoracic Retrieval team lead to contact Accepting Transplant Surgeon to discuss findings at retrieval.
- NORS Cardiothoracic Retrieval team lead to contact Lung ARC Clinical Lead to discuss findings at retrieval.
- NORS Cardiothoracic Retrieval team lead to inform SN of decision to either proceed with sending donor lungs to Lung ARC or to stand down sending donor lungs to Lung ARC.

SN to document outcome of these conversations on DonorPath.

**8.3.5 The Accepting Transplant Centre RCPoC must communicate any changes following this conversation with Hub Operations.**

Outcomes may be any of the following:

- Donor lungs to be sent to Lung ARC for EVLP. The Accepting Transplant Centre RCPoC to notify Lung ARC EVLP Operator and Hub Operations
- Donor lungs are found to be better than anticipated and a decision is made to send the lungs directly to the Accepting Transplant Centre for direct transplantation. The Accepting Transplant Centre RCPoC must notify the Lung ARC and Hub Operations.
- Donor lungs are declined and not to be sent to the Lung ARC for EVLP. The Accepting Transplant Centre RCPoC must notify the Lung ARC and Hub Operations. No changes to Hub process i.e. continue offering as per sequence (POL230).
- If Lungs are declined for both EVLP and direct transplant by all centres, lungs to be offered for research if organs are on the back bench and have appropriate research consent/authorisation in place.

**Note**

If lungs are fast tracked during retrieval, if time allows, wait for outcome of the fast track before sending lungs to the Lung ARC. It may be that lungs are accepted by a different centre and the requirements for an ARC change. If, however, lungs are explanted or are already enroute to the ARC, lungs should continue to the ARC. The ARC lead surgeon must confirm with Hub Operations that the lungs have been accepted and still require EVLP. Only once organ placement and requirement for EVLP confirmed should ARC proceed to undertake EVLP procedure.

**8.4 In Theatre Support, Collection, Labelling and Transport (Organ Samples)/ Organ Packing Guide for SN's and OPP**

The principles for packing lungs going to Lung ARC are unchanged. Follow Theatre Manual for Deceased Organ Donors for Theatre SOP5499 including handover of organs to transport personnel.

Transplant Unit Names and Addresses DAT3968 to be utilised to confirm ARC address for address labelling purposes

The Accepting Centre RCPoC has the responsibility to arrange transportation of the lungs from the donor hospital to the Lung ARC. The Accepting Centre RCPoC must communicate the estimated time of arrival with the ARC EVLP Operator.

**Note**

Pay careful attention to ARC address as this will be a different location to the usual Accepting Transplant Centre organ drop off address

**8.5 SENTINEL Trial**

If the donor is consented for and randomised for skin flap donation as per SOP6496 SENTINEL trial, the retrieved skin flap must be packed in accordance with SOP6496 and travel with the lungs to the Lung ARC.

## ***9. Arrival of Donor Lungs at Lung ARC***

---

Once donor lungs arrive at the Lung ARC they become the responsibility of the Lung ARC.

Refer to SOP6483 Lung Assessment and Recovery Centre (ARC)- Pilot Manual. Lung ARC to Transplant Centre from this point onwards.

**Training Plan: Internal NHSBT**

	<b>Trainee new to the process</b>	<b>Trainee trained to the previous revision.</b>
<b>Recommended Training Method</b>	<p>&lt;Training methods for each role/department identified e.g.:</p> <ul style="list-style-type: none"> <li>• Formal training package plus read through of SOP</li> </ul> <p><b>Include justification if training method is different from recommended training method&gt;</b></p>	<New document
<b>Assessment</b>	<p>&lt;How assessment of competency is evidenced e.g.:</p> <ul style="list-style-type: none"> <li>• FRM511</li> <li>•</li> </ul>	<New document
<b>Cascade Plan</b>	<p>&lt;Who will deliver the <i>Training Plan</i>, who will train the trainers e.g.:</p> <ul style="list-style-type: none"> <li>• Internal NHSBT - Author via live and pre-recorded session and cascade via Quality lead group and ODMT group.</li> </ul>	< New Document >

**Training Plan: External NHSBT**

	<b>Trainee new to the process</b>	<b>Trainee trained to the previous revision.</b>
<b>Recommended Training Method</b>	<p>&lt;Training methods for each role/department identified e.g.:</p> <ul style="list-style-type: none"> <li>• Training for ARC Champions to cascade</li> <li>• Read only as minimum</li> <li>• Enhanced by options Webinars – live and or recorded webinars made available on ODT microsite</li> </ul> <p>This is a bespoke method as this group of professionals are external to NHSBT &gt;</p>	<New document >

<b>Assessment</b>	<How assessment of competency is evidenced e.g.: <ul style="list-style-type: none"> <li>• ARC Champion Assurance</li> </ul>	< New document
<b>Cascade Plan</b>	<Who will deliver the <i>Training Plan</i> , who will train the trainers e.g.: <ul style="list-style-type: none"> <li>• Author training ARC champions and detail subsequent training responsibilities</li> </ul>	< New document

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

<b>Process Criticality Score</b>	<5>
----------------------------------	-----

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.
<b>Criticality of Change Score</b>	<4>

#### Training Plan Risk Matrix:

Criticality of Change	Process Criticality				
	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.

<b>Process Criticality Score</b>	<5>	
<b>Criticality of Change Score</b>	<4>	n/a
<b>Training Score</b>	<20>	n/a

**Recommended Training Method and Assessment:**

<b>Training Score</b>	<b>Level of Risk</b>	<b>Examples of Training Methods</b>	<b>Examples of Assessment</b>
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