SOP5352/7 – Findings During Retrieval Requiring Histopathology or Microbiology Assessment

Objective

During the Organ Retrieval Process there are occasions when suspicious lesions or findings are identified that require assessment from histopathology or microbiology. These are not a service provided or commissioned by NHSBT and the destination of samples can vary significantly.

This process provides guidance for all those involved in the histopathology or microbiology assessment of samples that may affect the safety of an organ, including SNODs, NORS teams, Histopathologists, Microbiologists, Biomedical Scientists, Hub Operations staff, and Receiving Centres.

Changes in this version

Change of title to add microbiology.
Addition of a new process if a collection requiring microbiology is found during retrieval.
Addition to documentation on DonorPath when new finding is identified.
Change from Email to report requiring 3 PID on reports.
Addition of MPD1086 regarding acceptable PID.
Change Clinical governance to Patient Safety.

Roles

- **National Organ Retrieval Team (NORS) –** Identify any lesion that may require histopathology assessment, gain advice where required and inform the SNOD as soon as lesion identified. To complete all relevant clinical information on National Request Form (**FRM5867**)
- **Specialist Nurse – (SN)** To facilitate the organisation of samples to be sent for histopathology assessment as agreed by the NORS surgeon and complete demographics on the National Histopathology Request Form (**FRM5867**). To communicate, report and document any findings requiring additional action that is identified during the organ donation process to Hub Operations. The SN is responsible for ensuring the provisional and final histopathology results are ascertained. SN to follow **SOP4938** for sharing of new clinical information.
- **Histopathology Laboratory –** Notify SN/Hub Operations of any findings or results following histopathology assessment.
- **Microbiology Laboratory –** Notify SN/ Hub Operations of any findings or results following microbiology assessment.
- **Hub Operations (HO) –** To follow **SOP4938** for sharing of new clinical information.
- **Receiving Centres–** To notify Hub Operations if there is any change in agreed process for assessment. To notify Hub Operations immediately if any new suspicious lesions are identified at organ assessment at the Recipient Centre as per **SOP5735**.
- **Donor Family Care Service (DFCS) –** To forward all histopathology findings to the SN as soon as they are received from Hub Operations. N.B. the DFCS is not a 24/7 service.

ADVICE

Three points of identification MUST always be present to ensure the correct identification of the donor as per Patient Identifiable Data (**MPD1086)**.

In some circumstances, a laboratory report may not have the appropriate identifier available in the allocated demographics area. In this case, the PID must be documented in the comment box of the report.

1- HISTOPATHOLOGY - If a lesion is identified during retrieval.

Instructions

This SOP is intended to support and advise the SN on steps when a need for histopathology is identified during deceased donor organ retrieval. Such findings require immediate assessment, communication, and an application of critical thinking by the SN and NORS Lead in theatre.

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

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

⚠ CAUTION

If a whole **organ** is being sent for histopathology, it must be sent with an organ for transplantation to a transplant centre or with the NORS team to ensure traceability. Please ensure this is recorded on the most appropriate HTA A Form. There is no requirement for the centre receiving the organ for histopathology testing to fill in a HTA B form.

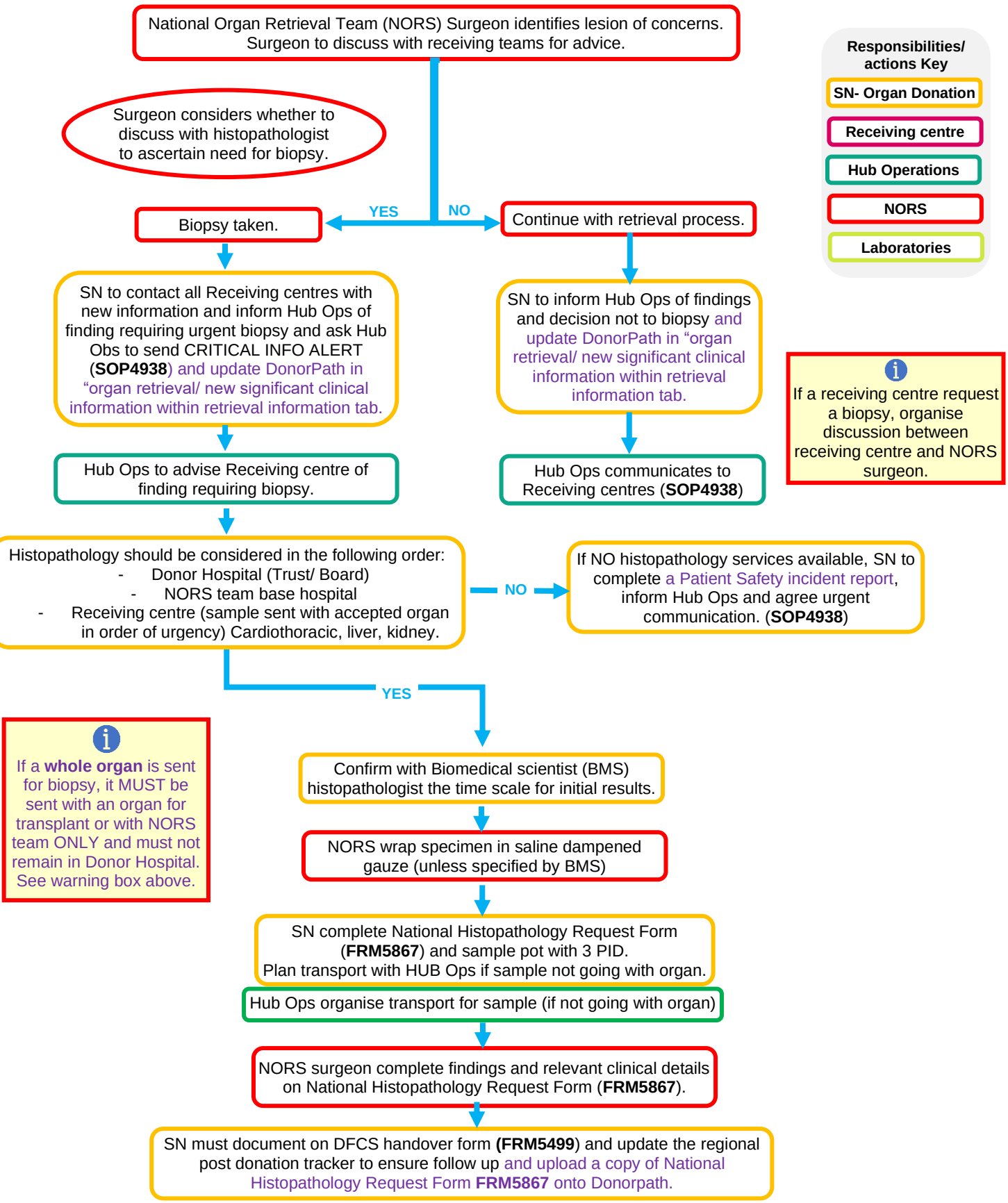
Care should be taken to ensure all options are explored however consideration must also be given to the type of donor DBD/DCD and the point in the retrieval process when the findings are made. Receiving centres must be made aware as fast as possible that there is a suspicious lesion (Cardiothoracic recipient surgery may already have commenced). For example:

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

On all occasions immediate findings must be communicated to all centres as per **SOP4938** Sharing Clinical Information.
The process below outlines the steps to be taken when histopathology resource is identified. On all occasions where samples are taken for histopathology **FRM5867** must be used which is available via the SN Donor Pack.

In circumstances where no histopathology is available resulting in stand-down of the deceased organ donors a Patient Safety notification should be made: https://www.odt.nhs.uk/odt-structures-and-standards/governance-and-quality/tell-us-about-an-incident/

Process when lesion found during retrieval (1/2)



Process when lesion found during retrieval (2/2)

SN informs Hub Ops of where histopathology will be completed and expected timescales for initial results confirming communication cascade (**SOP4938**)

Samples are processed on arrival by BMS/ Histopathology

If suspicious lesion is noted at the Receiving centre that was not noted during retrieval and a biopsy is taken, Hub Ops must be immediately contacted (**SOP5735**) to ensure all other centres are informed of findings.

If at any point a decision is made by anyone involved. NOT to process a sample or timescales are altered then ALL receiving centres MUST be informed (**SOP4938**) to ensure the decision does not impact on the implantation of any organs. This is still the case if it is felt the lesion is not suspicious.

Responsibilities/ Key actions

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

INTERIM REPORT

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

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

Hub Ops must disseminate to the SN (regional inbox) as per **SOP4938**.

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

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

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

FINAL REPORT

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

Hub Ops to the forward final report via secure email to SN (regional inbox) as per **SOP4938**.

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

SN to contact Receiving centre to advise new information available on TransplantPath as per **SOP4938**.

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

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

Instructions

This SOP is intended to support and advise the SN on steps when a need for Microbiology is identified during deceased donor organ retrieval. Such findings require immediate assessment, communication, and an application of critical thinking by the SN and NORS Lead in theatre.

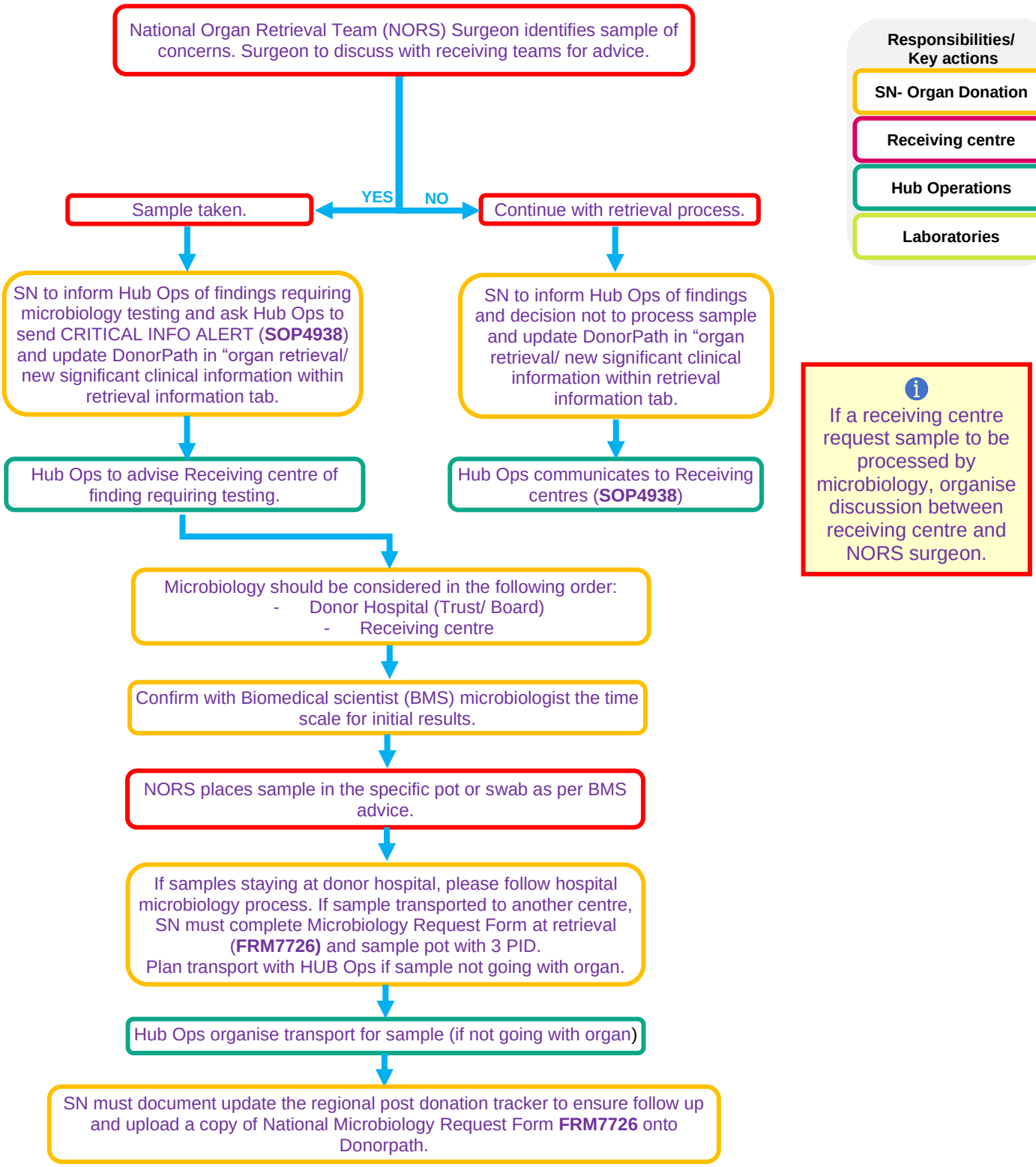
On all occasions access to microbiology should be considered in the following order:

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

Immediate findings must be communicated to all centres as per **SOP4938** Sharing Clinical Information.
The process below outlines the steps to be taken when microbiology resource is identified. On all occasions where samples are taken for microbiology **FRM7726** must be used which is available via the SN Donor Pack.

In circumstances where no microbiology is available resulting in stand-down of the deceased organ donors a Patient Safety notification should be made:
https://www.odt.nhs.uk/odt-structures-and-standards/governance-and-quality/tell-us-about-an-incident/

Process when sample requiring microbiology testing found during retrieval (1/2)



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

Responsibilities/ Key actions

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

SN informs Hub Ops of where microbiology will be completed and expected timescales for results confirming communication cascade (**SOP4938**)

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Samples are processed on arrival by BMS/ Microbiology

If a new finding is noted at the Receiving centre that was not noted during retrieval and a biopsy is taken, Hub Ops must be immediately contacted (**SOP5735**) to ensure all other centres are informed of findings.

If at any point a decision is made by anyone involved NOT to process a sample or timescales are altered, then ALL receiving centres MUST be informed (**SOP4938**) to ensure the decision does not impact on the implantation of any organs. This is still the case if it is felt the finding is not suspicious.

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

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SN to contact Receiving centre to advise new information available on TransplantPath as per **SOP4938**.

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

End of Procedure

Definitions

- **PID** – Personal/ Patient Identifiable Data

Related Documents / References

- **FRM5499 -** SN to DFCS Handover Form
- **FRM5867** – National Histopathology Request Form
- **FRM7726 –**Microbiology Request Form at retrieval
- **MPD1086 –** Patient identifiable data
- **SOP4938** – Clinical Information Sharing
- **SOP5735** – Findings at a Transplant Centre Requiring Histopathology

Document Details:

Document Title	Findings during retrieval requiring histopathology or microbiology assessment	
Document Number & Revision Number	SOP5352 version 7	
Type of Change	Change to existing process	
Stakeholders who require training	**Trainee new to the process**	**Trainee trained to the previous revision.**
	New specialist nurses	All Specialist nurses
Knowledge required prior to training	NA	Trained to previous version.
Critical aspects of process	During the Organ Retrieval Process there are occasions when suspicious lesions or findings are identified that require assessment from histopathology or microbiology. These are not a service provided or commissioned by NHSBT and the destination of samples can vary significantly. This process provides guidance for all those involved in the histopathology or microbiology assessment of samples that may affect the safety of an organ, including SNODs, NORS teams, Histopathologists, Microbiologists, Biomedical Scientists, Hub Operations staff, and Receiving Centres.	

Training Plan:

	Trainee new to the process	**Trainee trained to the previous revision.**
Recommended Training Method	Formal training package	Formal training package
Assessment	How assessment of competency is evidenced : • FRM511 •	<How assessment of competency is evidenced e.g.: • FRM511
Cascade Plan	• Author trains department managers or key trainers, who then cascade training to their department.	• Author trains department managers or key trainers, who then cascade training to their department.

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	3

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

	Change to Trainee(s)
1. Negligible	An existing process to which no material changes are made. E.g. format changes, minor clarifications of existing practice, fixing typos.
2. Minor	An existing process to which new information is added but where changes to existing knowledge and practices are minimal. E.g. clarifications that tighten existing practices

3. Moderate	An existing process of low complexity with material changes requiring different people to take action and/or people to change the tasks they perform. E.g. new roles/responsibilities, changes to the order of existing tasks, new tasks
4. High	A new process of moderate complexity, OR An existing process of moderate complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
5. Very High	A new process of high complexity, OR An existing process of high complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
Criticality of Change Score	3

Training Plan Risk Matrix:

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.
Process Criticality Score	3	
Criticality of Change Score	3	3
Training Score	9	9

Recommended Training Method:

Training Score	Level of Risk	Examples of Training Methods	Examples of Assessment
1 - 3	Low	Read only	Record on FRM511 only
4 - 8	Manageable	Email, team brief, word brief	Knowledge/Observation Check & FRM511
9 - 14	Medium/Significant	Formal training package	Knowledge/Observation Check & FRM511 or FRM5076
15 - 25	High	Practical	FRM5076 or equivalent