



PITHIA



Blood and Transplant

PITHIA Trial Laboratory SOP

Pre-Implantation Trial of Histopathology In renal Allografts



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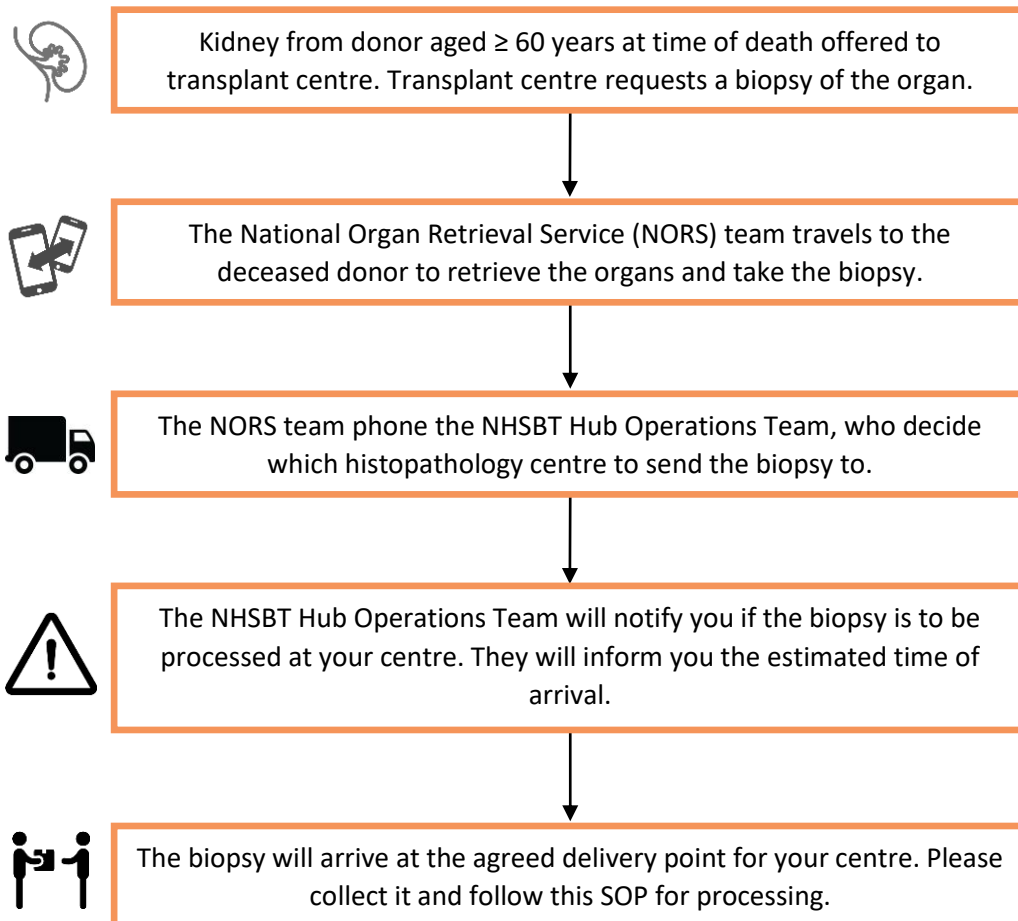
1.0 Contacts

PITHIA contacts are listed below. Please do not hesitate to contact us if you have a query related to the trial:

Emma Laing PITHIA Trial Manager	emma.laing@nhsbt.nhs.uk	01223 588091 07471 147868
Desley Neil PITHIA Lead Histopathologist	desley.neil@uhb.nhs.uk	07702 154389 07462 532026 0121 371 3349
NHSBT Hub Operations	odthub.operations@nhsbt.nhs.uk	0117 975 7580
General Enquiries	PITHIA@nhsbt.nhs.uk	01223 588091



2.0 PITHIA Specimen Flowchart





3.0 Notification of Specimen

NHSBT Hub Operations will contact you directly to notify you of specimen which is to be processed by your department. This notification will occur once the donor kidney has been retrieved and inspected by the retrieval surgeons. The Hub Operations team will be able to advise you of the Estimated Time of Arrival (ETA).

Agreed delivery point for your Trust:

WORKING HOURS:	OUTSIDE OF WORKING HOURS:
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Please make sure the Hub Operations team are informed if there are any likely problems with this on the day, so that an alternative delivery point can be agreed.

4.0 Transport of Specimen

The PITHIA biopsy will be a 4mm kidney punch biopsy.

The retrieval team will place the whole specimen (4mm kidney punch biopsy) in a formalin-filled pot and label with the following information:

- Donor ODT Number (plus **Left** or **Right** to indicate which kidney the sample was taken from)
- Donor Name
- Donor Date of Birth (DOB)
- Time biopsy taken
- Donor Hospital

The retrieval team will also complete the PITHIA Biopsy Request Form (shown in Appendix 1) and include it in the pack.





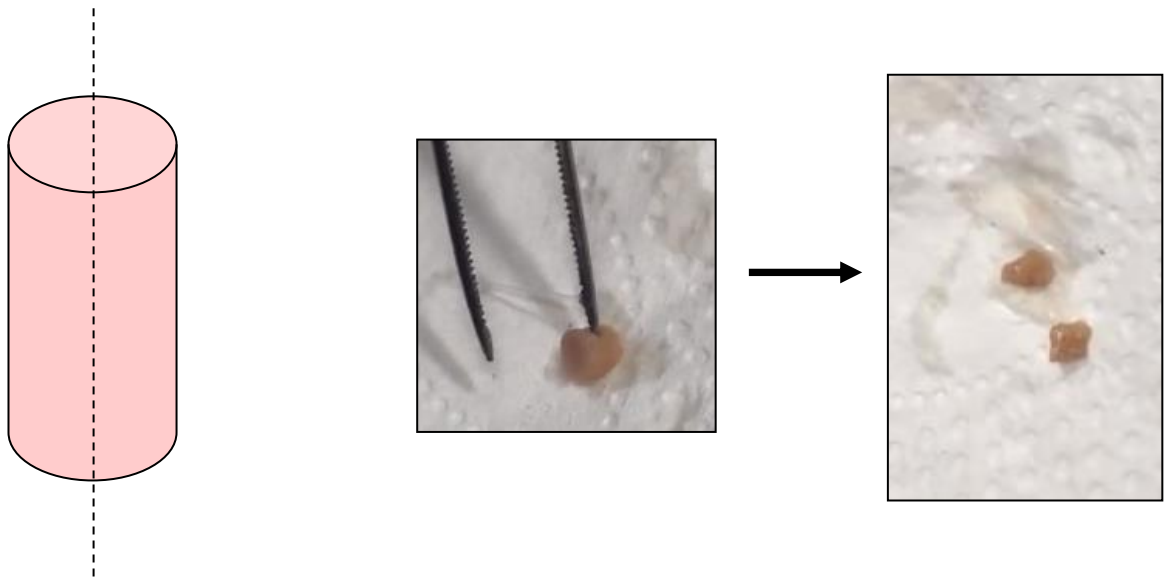
5.0 Receipt of Specimen

~~ If during the daytime (06:30 – 21:00), phone or text the on-call pathologist once you've received the specimen – to give advance notice. Details in Section 8.0 of this SOP. ~~

The specimen should be booked onto your Trust's Pathology system. The 'time taken' and 'time in formalin' will be documented on the Biopsy Request Form. If there are any queries related to the sample, contact the Retrieving NORS Team (contact details will be recorded on Biopsy Request Form).

Complete the bottom left section of the Biopsy Request Form. **Please retain these forms in your PITHIA file.**

On arrival at the laboratory (or after approx. 2 hours fixation time), the sample can be cut in half longitudinally before processing:



6.0 Processing Specimen

All PITHIA samples should be processed on a standard urgent run. This SOP is intended as a general guide, and local guidance should be sought if specific advice is required.

6.1 Precautions

Standard precautions for handling human tissue and hazardous substances. Wear suitable protective equipment.

6.2 Fixation

The sample will arrive in fixative (10% neutral buffered formalin). The fixation should be checked and augmented if required (using local protocols for urgent biopsies).



6.3 Embedding

Embed (cut surface(s) down) in paraffin.

6.4 Cutting

Cut a 10 slide serial.

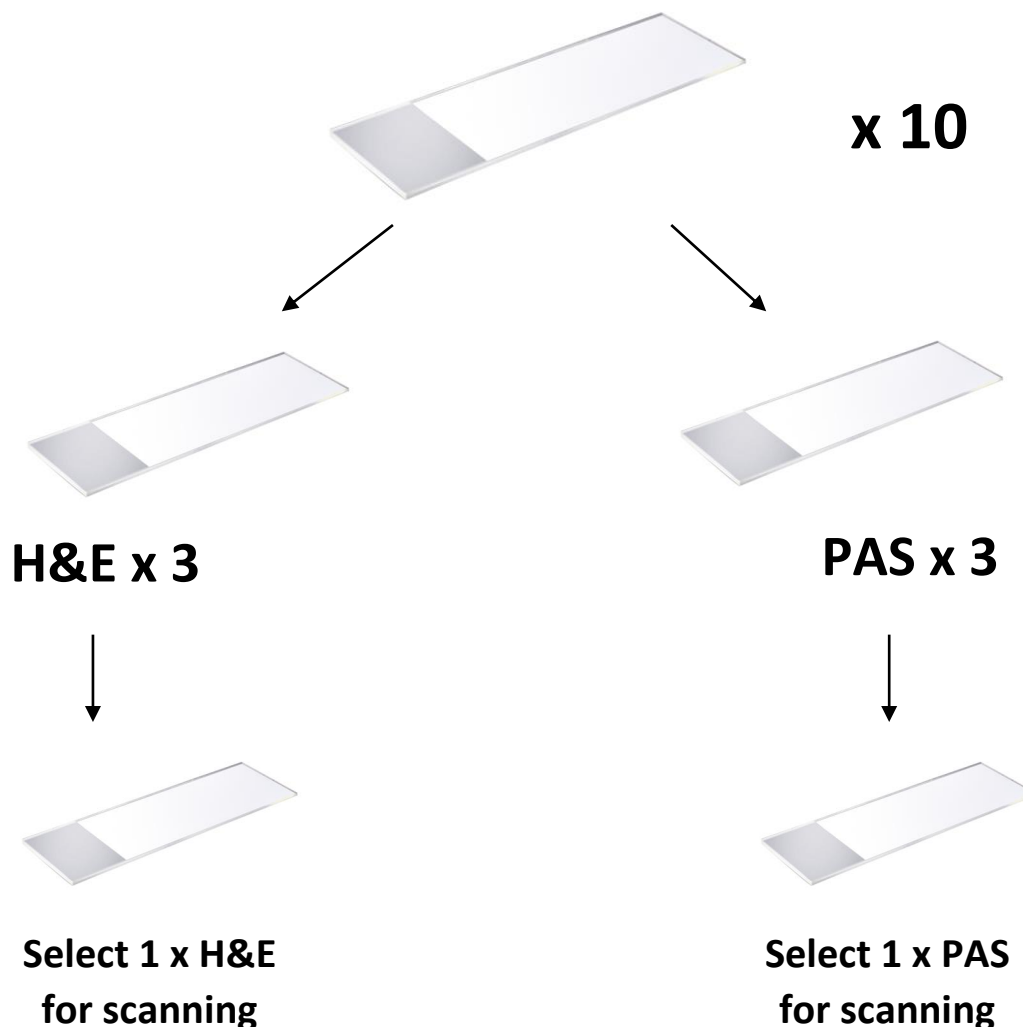
6.5 Staining

Stain three of the sections (*suggested sections: 1, 5 and 10*) with haematoxylin and eosin (H&E), as per standard local protocol.

Stain three of the sections (*suggested sections: 2, 6 and 9*) with periodic acid-Schiff (PAS), as per standard local protocol.

After staining, select the best section (1 of each stain), for scanning. Sections should be intact, without holes, not folded and showing the largest area of cortex.

SUMMARY:



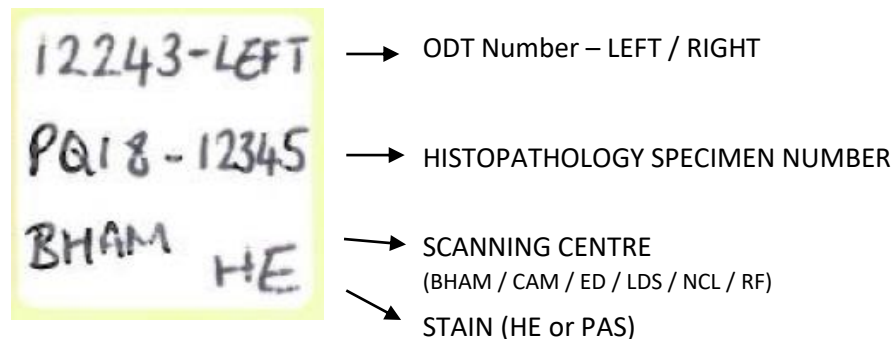


6.6 Slide Preparation

Coverslip the slides. Label with the following information ONLY (blank labels have been provided):

- ODT number (plus **LEFT** or **RIGHT** to indicate which kidney the biopsy was taken from)
- Laboratory number
- Scanner centre name (BHAM, ED, CAM, LDS, NCL, RF)
- Stain name

Example (glass slide label):



7.0 Scanning the Slides

Select two slides (1 H&E and 1 PAS) to scan. Label as shown in section 6.6.

The images should be scanned to CaseCenter (on Sysmex server) to enable the images to be viewed remotely (*further detail is contained within the **Pannoramic DESK Slide Scanner – User Guide for PITHIA Trial***).

Destination folder is ROOT DIRECTORY / PITHIA Trial / NOT YET REPORTED

Each slide should be named '[ODT NUMBER]-[LEFT/RIGHT]', e.g. 122431-LEFT. Once scanned, check the image and quality (for areas out of focus etc.). If poor scan quality, rescan the image(s).

<http://slides.sysmex.co.uk/CaseCenter/>

For log-in details, see table on next page. You must log-in using the correct username for your laboratory:



Laboratory	Username	Password
Birmingham	BHAM	<h1>SysmexUK</h1>
Cambridge	CAMB	
Edinburgh	EDINB	
Leeds	LEEDS	
Newcastle	NEWCL	
Royal Free	RFREE	

8.0 Notifying the on-call Histopathologist

Whilst scanning, the Histopathologist should be notified (even if they have already been made aware of the approximate scanning time). If during the daytime, the Histopathologist should have also been contact on receipt of the specimen. This is not required during the night (after 21:00 or before 06:30).

Check the PITHIA Histopathologist Rota to find out which Histopathologist should be sent the case to report. The on-call Histopathologist should be contacted **by telephone** and notified of the case. Sending a text message instead is acceptable provided the on-call Histopathologist acknowledges receipt.

On-call rota:



<http://www.pithia.org.uk/guidelines-for-professionals/>

Password: oracle

If no response, contact one of the Emergency Contacts which are listed on the website (underneath the calendar). If you have problems accessing the rota or have any queries related to this, please contact the PITHIA team (working hours) or NHSBT Hub Operations Team (out-of-hours).

Following initial contact with the Histopathologist, complete the bottom right section of the PITHIA Biopsy Request Form.

Send the completed form to the on-call Histopathologist via email (**nhs.net to nhs.net**) and copy odthub.operations@nhsbt.nhs.uk (confirmed secure as on N3 network). The Hub Operations team will then know to expect the Histopathology report.



Please refer to **PATHOLOGIST CONTACT SHEET** for on-call contact details.

Histopathologist Name (Surname, First Name)	Telephone Number(s)	Email Address

9.0 Storage of the Processed Specimen

Further work-up is not required. The blocks and slides should be stored according to local practice at your Trust. If the transplanting centre wish to perform additional work on the case, they will request the material.

10.0 Payment

The requesting hospital must not be charged for the biopsy request.

NHS England will pay £250 per biopsy processed to the participating Trusts in England.

NHSBT Clinical Trials Unit will maintain records of all PITHIA samples processed by each laboratory. It is recommended that a PITHIA Trial 'flag' is attached to the biopsy record in your Pathology system, and the following key points are recorded:

- H&E and PAS section scanned to PITHIA server
- Reported remotely as part of PITHIA trial
- No report on this system. Report emailed directly to NHSBT and implanting surgeon

11.0 Triggering temporary breaks

After receiving of a PITHIA sample outside of working hours, it is now possible for the laboratory BMS to trigger a 'temporary break' and prevent any further PITHIA samples being sent to your laboratory until the start of your laboratory's next working day*. This may be needed where one BMS is on-call for an extended period of time but should only be used where **absolutely necessary**.

*on Fridays/Saturdays, the re-start time should be 10:00am the following day.



PITHIA



Blood and Transplant

A template email has been provided to use (available on the PITHIA website). This must be sent to the Hub Operations Team Shift Managers (odthuboperations.shiftmanagers@nhsbt.nhs.uk) and clearly state in the email subject and body of the email which laboratory you are from:



PITHIA - INSERT LAB
NAME LAB TEMPOR/

www.pithia.org.uk/guidelines-for-professionals

Example email:

Send	From ▾	Emma.Laing@nhsbt.nhs.uk
	To...	ODT Hub Operations Shift Managers;
	Cc...	PITHIA; Laing Emma
	Bcc...	
	Subject	PITHIA - ROYAL FREE LAB TEMPORARY BREAK

Dear Hub Operations Managers,

Please do not send any PITHIA samples to **ROYAL FREE** lab until **08:00** ON **25/02/2020**.

Thank you.

Kind regards,

Emma

Emma Laing

*Clinical Trial Manager, Clinical Trials Unit
NHS Blood and Transplant*

Tel: 01223 588091

Mobile: 07471 147868

Visit: www.nhsbt.nhs.uk/clinical-trials-unit

This trigger cannot be used after being notified of an incoming sample.

Please copy in PITHIA@nhsbt.nhs.uk and emma.laing@nhsbt.nhs.uk.



APPENDIX 1

PITHIA BIOPSY REQUEST FORM_v1.3_2018_12_03



PITHIA — BIOPSY REQUEST FORM

NHSBT HUB CONTACT DETAILS:

Telephone: 0117 975 7580

Email: odthub.operations@nhsbt.nhs.uk



THIS FORM MUST BE SENT WITH THE PITHIA BIOPSY

RETRIEVING NORS TEAM NORS Team: NORS Surgeon Contact Name: Telephone: SNOD Contact Name: Telephone:		REQUESTING CENTRE Recipient Centre:	
DONOR ODT Number: Left / Right Kidney: NHS/CHI Number: Donor Name: Date of Birth: Donor Hospital: Donor Type: <input type="checkbox"/> DBD <input type="checkbox"/> DCD		SPECIMEN Specimen type: Date taken: Time taken: Time in formalin:	
DONOR CLINICAL DETAILS Relevant Past Medical History: <input type="checkbox"/> Diabetes <input type="checkbox"/> Hypertension <input type="checkbox"/> Other: specify Cause of Death: Latest creatinine result: Intra-operative findings (if relevant):			
BIOPSY TRAVEL (DISCUSS WITH NHSBT HUB) <input type="checkbox"/> With NORS team to base (if scanner centre) <input type="checkbox"/> With a retrieved abdominal organ <input type="checkbox"/> Independent transport required (TNT) Scanner Centre (select): <input type="checkbox"/> Cambridge <input type="checkbox"/> Birmingham <input type="checkbox"/> Edinburgh <input type="checkbox"/> Leeds <input type="checkbox"/> Newcastle <input type="checkbox"/> Royal Free, London			
TO BE COMPLETED BY SCANNER CENTRE ON RECEIPT OF SAMPLE			
Time Received: Histopathology number: BMS Contact Name: Telephone:		Please send this form to the on-call Histopathologist, and complete the details below: On-Call Histopathologist Name: Telephone: Email:	
<i>On-call Histopathologist rota can be found at www.pithia.org.uk or by contacting the Hub.</i>			

IMPORTANT NOTE for Histopathologist:

Should the biopsy identify pathology that is, or may be, relevant for the health or future health of the transplant recipient(s) please contact the Hub Operations as a matter of urgency on 0117 975 7580.



APPENDIX 2 – TECHNICAL ASSISTANCE

Sysmex UK Customer Service Centre (09:00 - 17:30):

Product Hotline – 0333 320 3466

For queries about software settings and slide scanner adjustments etc.

Service Hotline – 0333 320 3467

For technical errors and instrument breakdowns

Out of hours – leave a message on the Service Hotline and your call will be given highest priority when the Customer Service Centre is open again. **You must also inform NHSBT Hub Operations if any fault occurs which means you will not be able to scan the images.**

Please make sure you state where you are calling from and note the serial number of the slide scanner:

PDESK-026610 Queen Elizabeth University Hospital, Birmingham
PDESK-026310 Royal Infirmary of Edinburgh
PDESK-026210 Royal Free Hospital
PDESK-026110 Royal Victoria Infirmary, Newcastle
PDESK-026510 Addenbrooke's Hospital
PDESK-026710 St James University Hospital, Leeds