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	Author:		Zeeshan Akhtar		
	Approver:		Jon Milton		
Title					
Collection of QUOD Samples by Abdominal NORS Team					
Summary of Significant Changes					
Date	Details of Review	Version Number	No. of pages	Reviewer	Next Review
30 Jul 2013	Remove “Staff Record of Acknowledgment” section.	7	10	Sandrine Rendel	30 Jul 2015
03 Feb 2014	Review of lab liaison role in lieu of ROC in Split Regions, clarification of Scrub Nurse / Theatre Practitioner handover in tissue collection, new bagging of QUOD box step to waterproof box in wet ice during transit.	8	12	Dawn Howe	03 Feb 2016
14 Feb 2014	Changing the length setting of the biopsy gun from 23mm to 33mm and information about the QUOD Box receipt sticker.	9	11	Dawn Howe	14 Feb 2016
16 Jul 2014	More details on biopsy sites for kidney and liver biopsies. Inclusion of requirement for a proline suture after kidney biopsies	10	11	Sandrine Rendel	16 Jul 2016
18 Dec 2014	Additional details of liver biopsy site and suture requirement (3), requirement to record blood centrifugation time and clarification on when to centrifuge DB3 and DB4 sets (7)	11	12	Sandrine Rendel	18 Dec 2016
08 Apr 2014	Further information regarding paediatric donors included (p4 &p6)	12	12	Sandrine Rendel	08 Apr 2015
25 Oct 2017	Further information regarding liver biopsy technique	13	15	Sandrine Rendel	25 Oct 2019

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12 Jan 2018	Changes to the kidney biopsy collection technique	14	16	Sandrine Rendel	12 Jan 2020
12 Dec 2018	Further information regarding kidney biopsy site suture and inclusion of heart biopsy samples from non-allocated hearts	15	18	Sandrine Rendel	12 Dec 2020
12 Jun 2019	Change of protocol for kidney biopsies (QUOD and PITHIA)	16	18	Sandrine Rendel	12 Jun 2021
24 Jun 2021	2 year review. Change to formatting	17	15	Sarah Cross	24 June 2023
12 Jan 2022	Inclusion of kidney biopsy priority guidelines	18	16	Sarah Cross	12 Jan 2024
4 Feb 2022	Removal of all references to PITHIA (study has finished)	19	16	Sarah Cross	4 Feb 2024
25 Apr 2022	Changes to kidney and non-transplantable heart biopsy technique	20	16	Sarah Cross	25 Apr 2024

You are instructed to read the following thoroughly before proceeding to undertake the methods described.

Under no circumstances are these instructions to be amended or altered other than by authorised members of the National Management Team.

Purpose

The purpose of this document is to inform and guide the Theatre Practitioner/NORS surgeon in receiving the QUOD box from the SNOD, obtaining the relevant blood, urine and tissue biopsy specimens and handing them out to the appropriate QUOD member for processing.

Relevance

This SOP applies to all QUOD trained Theatre Practitioners and members of the NORS team

<i>Responsibilities</i>	<i>Definitions</i>
<p>SNOD – to make sure specific consent/authorisation for QUOD research has been gained before obtaining samples. To transfer samples to the NORS team on their arrival. To follow the NHSBT SOP regarding donor consent for research samples.</p> <p>Theatre Practitioner –to obtain and process blood, urine and tissue samples (once removed by the surgeon) for QUOD in theatre. To follow this SOP.</p> <p>Scrub Nurse – to assist in the sample collection where needed.</p> <p>NORS Surgeons – to accept custodianship of the QUOD samples and transportation of these back to the QUOD centre and to assist in the</p>	<p>QUOD – Quality in Organ Donation programme</p> <p>NHSBT – National Health Service Blood and Transplant</p> <p>SNOD – Specialist Nurse in Organ Donation. For the purposes of this document the terminology "SNOD" will apply to either Specialist Nurse or Specialist Practitioner with the relevant knowledge, skills and training in organ donation, working within NHSBT Organ Donation Services Teams (ODST)</p> <p>Theatre Practitioner – the terminology "Theatre Practitioner" applies to the person who has been designated to obtain and process blood, urine and tissue samples (once removed by the surgeon) for QUOD in theatre, this person can also be known as the perfusionist</p> <p>NORS surgeons – National Organ Retrieval Service.</p>

<p>procurement of tissue biopsies.</p> <p>Laboratory staff in donor hospital– to release the relevant blood samples for QUOD to the SNOD.</p> <p>QUOD and NHSBT – to ensure all staff are trained appropriately.</p>	<p>ROC – Regional Operational Coordinator</p> <p>DB1 – 1st set of blood samples. These should be samples taken from the donor as close to hospital admission as possible. They are requested retrospectively by the SNOD from the laboratory of the donor hospital</p> <p>DB2 and DU2 – 2nd set of blood and urine samples. To be obtained as soon as consent/authorisation has been agreed.</p> <p>DB3 and DU3 – 3rd set of blood and urine samples. To be obtained just before going to theatre.</p> <p>DB4 and DU4 (DBD) – 4th set of blood and urine samples. To be obtained from a DBD only, following knife to skin and before cross-clamp</p>
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References & Related Documents	
<p>FRM4281 & FRM1538 NHSBT & SNBTS Consent/Authorisation Forms</p> <p>CD001 & CD003 QUOD Relative Information Leaflets</p> <p>CD002 QUOD sticker for NHSBT Consent/Authorisation Form</p>	<p>WD003 QUOD Worksheet</p> <p>WD009 Lab Liaison QUOD Box Content Check</p> <p>SOP024 Collection of heart biopsies and BAL</p>
Safety Information	
<ol style="list-style-type: none"> 1. Comply with the local Health and Safety rules at all times. 2. All samples must be treated as potentially infectious. 3. All aspects of the task, which fall outside of the NORS team current job description, are assessed in the Risk Assessment SAF003 – Collection of QUOD samples by NORS team. Please read this associated Risk Assessment before performing the task. 4. Personal Protective Equipment must be worn when handling samples. 	

Procedure

<p style="text-align: center;">On leaving the QUOD centre:</p> <p>When the retrieval team is called out for organ retrieval on QUOD donor, the team should make sure that they take with them:</p> <ul style="list-style-type: none"> - Centrifuge in the bag provided by QUOD, which also contains the Quick Reference guide (WD001) and a set of counterweights for the centrifuge - A small stock of biopsy instruments provided by QUOD, which should be monitored by the local ROC in coordination with the local Theatre Practitioners - A new unopened QUOD box to be handed over to the SNOD currently on site
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Note on Paediatric Donors:

Paediatric donors over the age of 5 years are now in scope for QUOD for blood and urine samples only (tissue samples and biopsies from paediatric donors should NOT be taken)

Once consent/authorisation has been obtained and the initial blood and urine samples have been collected by the SNOD (DB1, DB2/DU2 and DB3/DU3), the QUOD box is handed over to the NORS team. The retrieval team should also give a new QUOD box, brought from the NORS centre, to the SNOD to replenish their stock of QUOD boxes

Collection of DB4 and DU4 (DBD only):

The Theatre Practitioner is responsible for the collection of samples DB4 and DU4 (DBD only). If there is no Theatre Practitioner then the responsibility to arrange for collection of the DB4 and DU4 samples should be decided by the retrieval surgeon

1. DB3 blood sample centrifugation

- 1.1. Centrifuge the DB3 samples (and DB2 samples if in the QUOD box) before the organ retrieval procedure starts in theatre
- 1.2. Take the centrifuge out of the bag, place on a level surface and plug in. See the quick reference guide for details on how to set up the centrifuge
- 1.3. Blood tubes that have been kept at room temperature (RT) are placed in the centrifuge. Use a counter-weight tube (found in centrifuge bag) if needed to balance the rotor of the centrifuge.
- 1.4. Allow SST (gold top) to clot for 30-60 minutes then spin along with the EDTA (pearl top) and heparin (green top) @ 3700 RPM, set the centrifuge at 37 on the display (equivalent to 1300 RCF) for 15 minutes
- 1.5. Once spun, remove the tubes from the centrifuge and place in the correct location in the QUOD box using the labels under the barcode, the sample names from the worksheet and the box map on the front panel of the box as a reference
- 1.6. Record the centrifugation times of the blood samples in the dedicated columns on the QUOD worksheet
- 1.7. If DB1 samples were sourced by the SNOD and handed over to be kept on ice, remove these from the sample bag and add them to the QUOD box in the designated space for DB1 samples

2. DB4 collection (DBD only)

- 2.1. Just prior to cross clamp request and obtain DB4 blood samples
- 2.2. Identify the DB4 sample containers in the QUOD Box
- 2.3. Hand these to the anaesthetist who will take the samples using the provided containers and blood tube adaptors found in the QUOD box
- 2.4. Request the samples DB4 just prior to cross clamp

- 2.5. Ensure the containers are filled to the minimum level and that the vacutainers are inverted at least 8 times to allow the additives to be mixed evenly
- 2.6. Spin down DB4 as soon as convenient (except SST serum - allow to clot for 30-60min)
- 2.7. Place these samples back into the DB4 section of the QUOD box and store on ice in the cold box used to keep the perfusion fluid cold
- 2.8. Complete the appropriate section of the QUOD worksheet

3. DU4 collection (DBD only)

- 3.1. Identify the DU4 sample container in the QUOD box and obtain the sample prior to cross clamp using the provided container
- 3.2. Ensure sample is collected from the hourly urine output chamber (sub-chamber) rather than from the main collection bag. If no sub-chamber exists urine can be aspirated from the catheter
- 3.3. Ensure the container is filled to the minimum level (top of the barcode)
- 3.4. Place this sample back into the DU4 section of the QUOD box and store on ice in the cold box used to keep the perfusion fluid cold
- 3.5. Complete the appropriate section of the QUOD worksheet

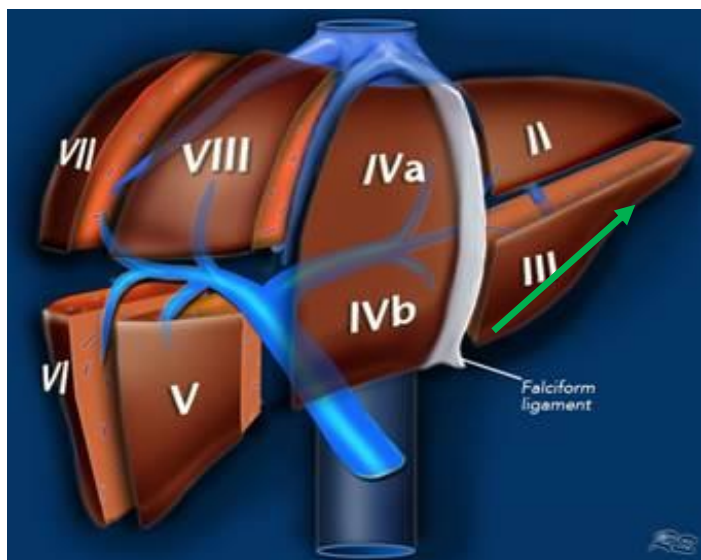
It is important to identify the correct samples from the QUOD Box to ensure that samples are taken in the right order

The DB4 and DU4 samples will be pre-labelled with the unique QUOD barcode– no patient identifiable information should appear on the sample containers

Tissue collection (Adults only)

Tissue biopsy specimens will be taken by the NORS retrieval surgeon and handed to the Theatre Practitioner who will ensure samples are placed in the appropriate tubes in the QUOD box

Liver biopsy guide:



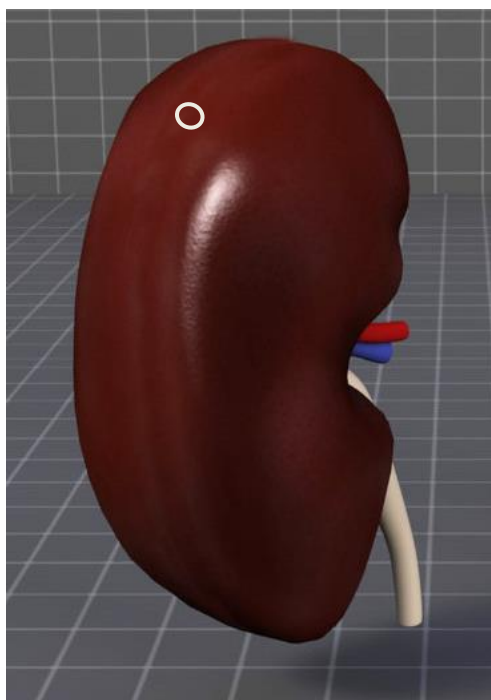
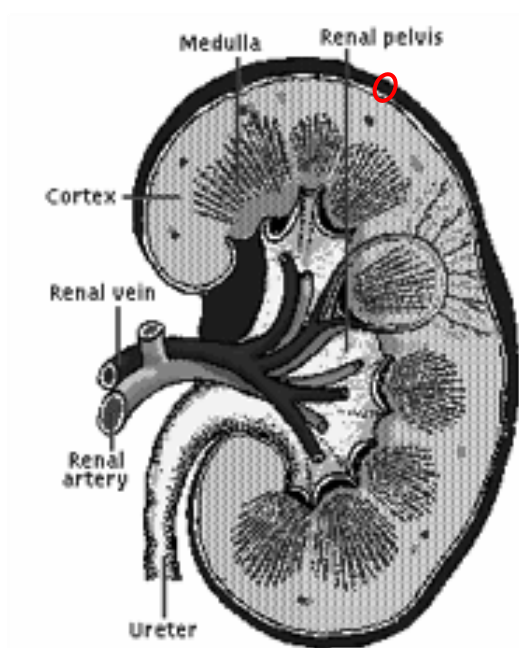
Cautionary notes:

Please note that incorrectly performed liver biopsy may result in:

- Intra-operative bleeding
- Bile leaks
- Internal arterio-venous fistula
- Hepatic artery pseudoaneurism
- Liver abscess
- Graft and patient loss as a consequence

Following the correct procedure avoids and helps minimise such complications. See pages 9-11 for more details.

Kidney biopsy guide:



The red and white circles show the advised site of the punch biopsy.

See pages 8 and 12 for more details.

Kidney biopsy priority guidelines

NHSBT facilitates research and NORS Teams are required to obtain samples during retrieval for QUOD or projects agreed by RINTAG, where appropriate consent/authorisation has been obtained.

There is a potential conflict when a research biopsy (e.g. QUOD) is considered in a donor where an organ may have undergone a biopsy for clinical assessment purposes. Kidney biopsies in particular have led to governance incidents. Therefore, the SNOD and the lead surgeon must consider the following priorities specifically for **kidney biopsy**.

Priority 1.

Organ Safety Assessment.

These biopsies are obtained as there is concern relating to malignancy or other serious disease. Adequate material should be taken to secure a pathological diagnosis, excluding or confirming the diagnosis definitively. Biopsies may be wedge, punch or other as appropriate. The NORS surgeon **must discuss with recipient centres**.

Priority 2.

Organ Quality Assessment.

Such biopsies are taken on the clinical request of the implanting centre for their allocated kidney to determine quality. A punch biopsy is recommended. Only one quality assessment biopsy should be taken from that kidney. A quality assessment biopsy may be taken in addition to an organ safety assessment biopsy (Priority 1), if deemed necessary and **requested** by the recipient centre.

Priority 3.

QUOD Biopsies.

QUOD (research) biopsies should only be taken if **no other biopsies are requested or taken**. Only one attempt should be made to take a QUOD biopsy, and only one QUOD biopsy should be taken from a kidney.

*For the avoidance of doubt, if a biopsy has been taken for organ safety and/or organ quality, **a further research biopsy must not be taken.***

Kidney biopsy guide:

Please perform the QUOD kidney biopsy with a 3mm punch biopsy device provided by QUOD



Place the biopsy instrument at the upper pole of the kidney and twist clockwise and anticlockwise pressing in until the metal part is fully inserted into the kidney

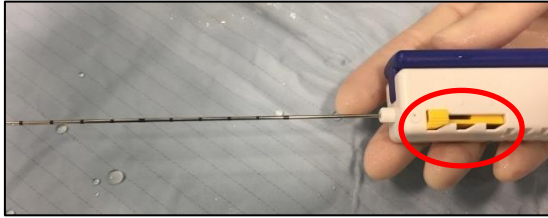


Pick the biopsy up with forceps to expose the bottom



Lift the biopsy and slice the bottom edge of it with a scalpel

Liver biopsy guide:

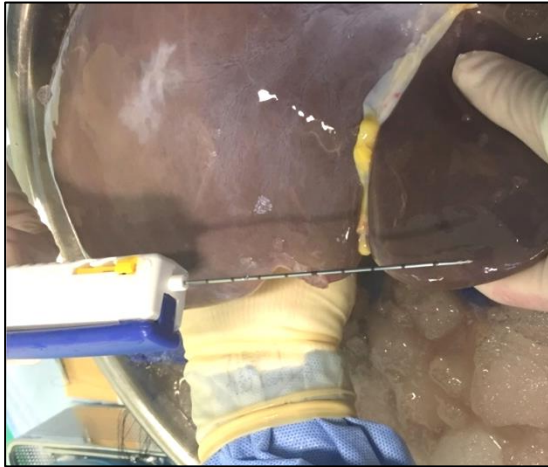


Surgeon assembles BioPince device removing the protective sheath surrounding the biopsy needle.

The size needs to be left on the **default setting at 33mm**



DO

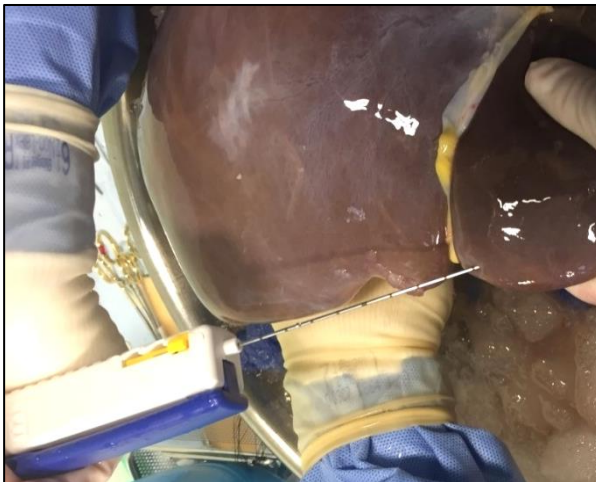


Prior to insertion of biopsy needle **PLAN** the biopsy needle entry and intrahepatic course of needle as follows:

- **Needle entry** should be at the tip of the Segment III where falciform ligament is attached
- The **intrahepatic course of the needle** should run parallel to the margin of the left lobe, not more than 1cm away from it
- The image shows the ideal direction of the needle



DO



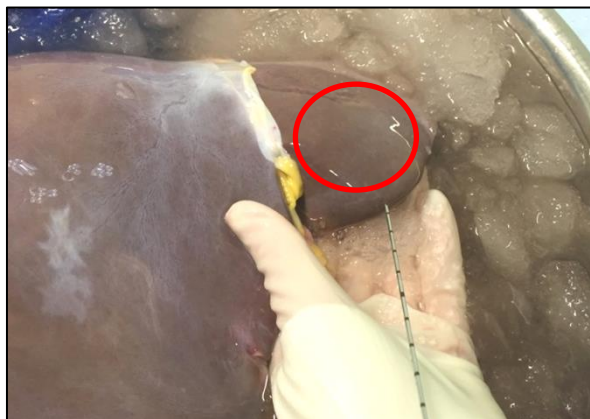
Surgeon inserts needle into at the tip of Segment III where falciform ligament is attached and aiming away from the falciform ligament, following the edge of the liver.

Please make sure biopsies are peripheral and along the edge of the liver and do not go close to pedicles

Please note the direction of needle as it is inserted - correct orientation is the key to obtain a safe peripheral biopsy

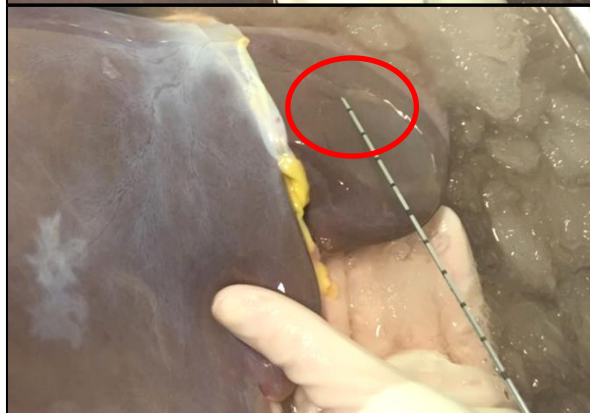
Liver biopsy guide:

X DO NOT



Please **DO NOT AIM** the needle in the direction of the centre of the left lateral segment – the danger area of hitting intrahepatic pedicular structures is shown in red circle.

X DO NOT



Please **DO NOT INSERT** the needle at the centre of the left lateral segment – the danger area of hitting intrahepatic pedicular structures is shown in red circle.

X DO NOT



Please **DO NOT INSERT** the needle at the centre of the left lateral segment in the direction shown here – the danger area of hitting intrahepatic pedicular structures is shown in red circle.

4. Liver biopsy (DBD/DCD, specimen taken ex-situ on back table)

- 4.1. Theatre Practitioner removes outer packaging for BioPince biopsy device
- 4.2. Surgeon assembles device, removing protective sheath surrounding biopsy needle. The size needs to be left on the default setting at 33mm
- 4.3. Surgeon inserts needle into surface of the left liver lobe in segment 3, perpendicular to and aiming away from the falciform ligament, following the edge of the liver (see diagrams on pages 9 and 10). Please make sure biopsies are peripheral and along the edge of the liver and do not go close to pedicles
- 4.4. Fire gun when ready to take the biopsy. Once fired remove needle from liver
- 4.5. Stitch the biopsy site with a 5.0 prolene closing suture
- 4.6. Expel biopsy specimen onto clean wet swab - handle biopsies with care. Ensure biopsies are handled at the cut end to ensure no destruction of tissue architecture
- 4.7. Hand swab out to Scrub Nurse
- 4.8. The Scrub Nurse will divide the biopsy specimen into two on a wet swab using a blade.
- 4.9. The Theatre Practitioner will identify and remove the two liver biopsy tubes from the QUOD box – DL formalin; Liver formalin, DL RNA: Liver RNAlater. Unscrew the caps, ready to receive the two halves of the liver biopsy from the Scrub Nurse
- 4.10. One half of the biopsy should be stored in RNAlater and the other half in formalin
- 4.11. The Theatre Practitioner will securely replace the tube lids and return the tubes to the appropriate section of the QUOD box, to be stored on melting ice
- 4.12. Complete appropriate section on QUOD worksheet

The RNAlater and formalin sample pots will be pre-labelled with the unique QUOD barcode – no patient identifiable information should appear on the sample containers

Please ensure the biopsy is recorded on the HTA A form – this is the only way to inform the transplant surgeon that a biopsy has been taken

A sticker is provided by QUOD to be added to the form (please record on each page)



5. Kidney biopsy (DBD/DCD, specimen taken ex-situ on back table)

- 5.1. Theatre Practitioner removes outer packing of the Stiefel Disposable Biopsy Punch instrument (3mm diameter)
- 5.2. Surgeon inserts punch biopsy instrument into the upper pole of the kidney and twists clockwise and anticlockwise pressing in until the metal part is fully inserted into the kidney (see diagrams on page 8)
- 5.3. Remove the biopsy by grasping at its base (i.e. near the cortico-medullary junction) with the forceps, and transecting to expose its base (i.e. near the cortico-medullary junction). Slice as close to the base as possible with a pair of dissecting scissors. The aim is to remove a core that is 7-8mm in depth
- 5.4. **When a biopsy is being taken for QUOD, the retrieval surgeon only does the biopsy, the implanting transplant surgeon attends to the haemostasis. Please ensure the implanting transplant team is made aware that a biopsy was taken by recording it on the HTA A form (sticker provided to NORS teams)**
- 5.5. Hand swab to Scrub Nurse
- 5.6. The Theatre Practitioner identifies the correct kidney biopsy tubes for the kidney being handled (i.e. left or right kidney) –
 - the biopsy from the left kidney is placed into formalin: DLK Formalin
 - the biopsy from the right kidney is placed into RNAlater: DRK RNA
 - If only one kidney is biopsied, please place this biopsy into RNAlater and add as a variance on the QUOD worksheet
- 5.7. The Theatre Practitioner removes the two kidney biopsy tubes from the QUOD box and unscrews the caps, in order to receive the kidney biopsies from the Scrub Nurse.
- 5.8. The Theatre Practitioner securely replaces the tube lids and returns the tubes to the QUOD box, to be stored on melting ice
- 5.9. Complete appropriate section on QUOD worksheet
- 5.10. Repeat this process (5.1 to 5.9) for the other kidney.

The RNAlater and formalin sample pots will be pre-labelled with the unique QUOD barcode – no patient identifiable information should appear on the sample containers

Please ensure the biopsy is recorded on the HTA A form – this is the only way to inform the transplant surgeon that a biopsy has been taken

A sticker is provided by QUOD to be added to the form (please record on each page)



6. Left ureteric biopsy (DBD/DCD, specimen taken ex-situ on back table)

- 6.1. Surgeon to cut an approx. 1cm length of left ureter (when not possible to take a sample from the left ureter, please take a specimen from the right ureter)
- 6.2. Place ureter onto clean wet swab
- 6.3. Hand swab out to Scrub Nurse
- 6.4. The Scrub Nurse will divide the biopsy specimens into two on a wet swab using a blade
- 6.5. The Theatre Practitioner will identify and remove the two ureter biopsy tubes from the QUOD box – DLU Formalin: Ureter formalin; DLU RNA: Ureter RNAlater. Unscrew the caps, ready to receive the two halves of the ureter biopsy from the Scrub Nurse.
- 6.6. One half of the biopsy should be stored in RNAlater and the other half in formalin
- 6.7. The Theatre Practitioner will securely replace the tube lids and return the tubes to the QUOD box, to be stored on melting ice
- 6.8. Complete appropriate section on QUOD worksheet

The RNAlater and formalin sample pots will be pre-labelled with the unique QUOD barcode – no patient identifiable information should appear on the sample containers

7. Splenic biopsy (DBD/DCD, specimen taken ex-situ on back table)

- 7.1. Cut an approx. 1cm x 1cm piece of spleen
- 7.2. Place the splenic sample onto clean wet swab
- 7.3. Hand swab out to Theatre Practitioner
- 7.4. The Theatre Practitioner will store the whole tissue sample in RNAlater.
- 7.5. Identify the splenic biopsy tube filled with RNAlater in the QUOD box (Spleen: Spleen RNAlater) and place the sample in. Return the tube to the QUOD box, to be stored on melting ice
- 7.6. Complete appropriate section on QUOD worksheet

The RNAlater sample pot will be pre-labelled with the unique QUOD barcode– no patient identifiable information should appear on the sample container

8. Heart biopsy

Biopsies are taken only from hearts not accepted for transplantation

For DCD hearts: Biopsies to be taken following cardiac arrest

For DBD hearts: Biopsies to be taken after cross-clamp

Note:

When Cardiothoracic team is present, they will collect the heart biopsies

For donors only attended by the Abdominal team, heart biopsies will be taken by the Abdominal team

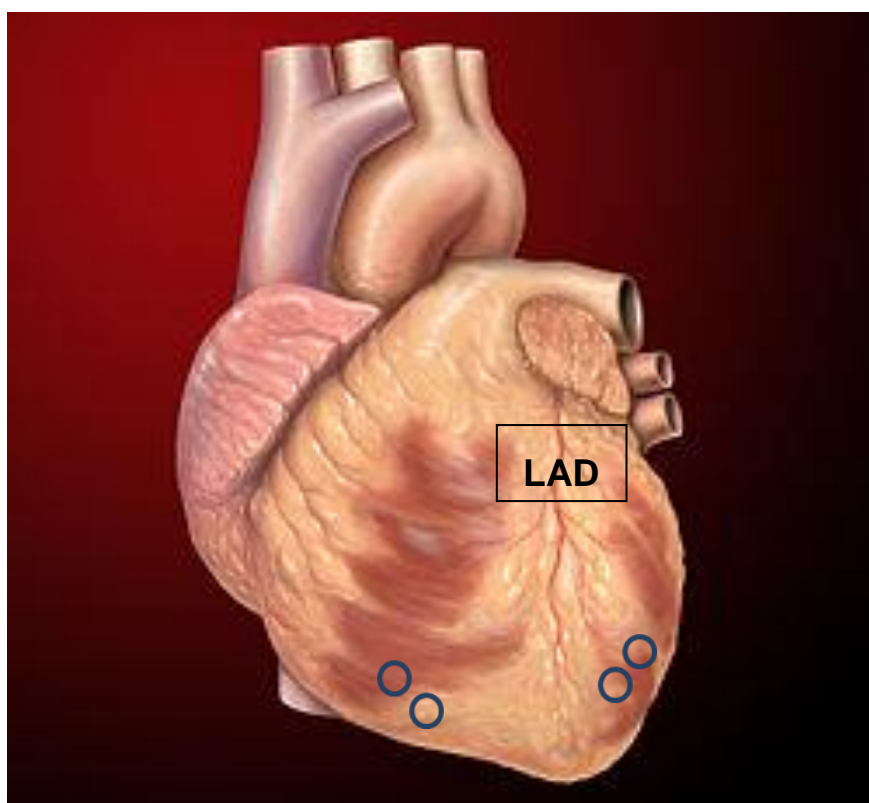
- 8.1. Heart biopsy specimens are taken ex-situ on the back-table (or in-situ if the heart is not removed). Biopsies are collected from both Left and Right ventricles
- 8.2. Theatre Practitioner removes outer packaging for 4mm punch biopsy device
- 8.3. Surgeon inserts full thickness of the 4mm diameter skin biopsy puncher 2cm medial and 2cm lateral to LAD (see image below). Each ventricle should be biopsied twice. Care should be taken to biopsy muscle of the free wall, and not epicardial fat on both right and left ventricles
- 8.4. Using forceps, hold the biopsy and pull slightly. Use a scalpel to cut the biopsy at the base. Place biopsy onto a swab
- 8.5. Repeat step 8.3 to take the other 3 biopsies. Handle biopsies with care. Ensure biopsies are handled at the cut end to ensure no destruction of tissue architecture
- 8.6. Hand swab out to Scrub Nurse, taking care to identify clearly which are left and which are right ventricle biopsies
- 8.7. The Theatre Practitioner will identify and remove the four heart biopsy tubes from the QUOD box (DHR formalin: Heart Right ventricle formalin; DHR RNA: Heart Right ventricle RNAlater; DHL formalin: Heart Left ventricle formalin; DHL RNA: Heart Left ventricle RNAlater). Unscrew the caps, ready to receive the heart biopsies from the Scrub Nurse
- 8.8. For both right and left ventricle samples, one full biopsy should be stored in RNAlater and the other in formalin
- 8.9. The Theatre Practitioner will securely replace the tube lids and return the tubes to the QUOD box, to be stored on melting ice
- 8.10. Complete appropriate section on QUOD worksheet

The RNAlater and formalin sample pots will be pre-labelled with the unique QUOD barcode – no patient identifiable information should appear on the sample containers

4mm punch biopsy instrument



Punch biopsies of the Heart



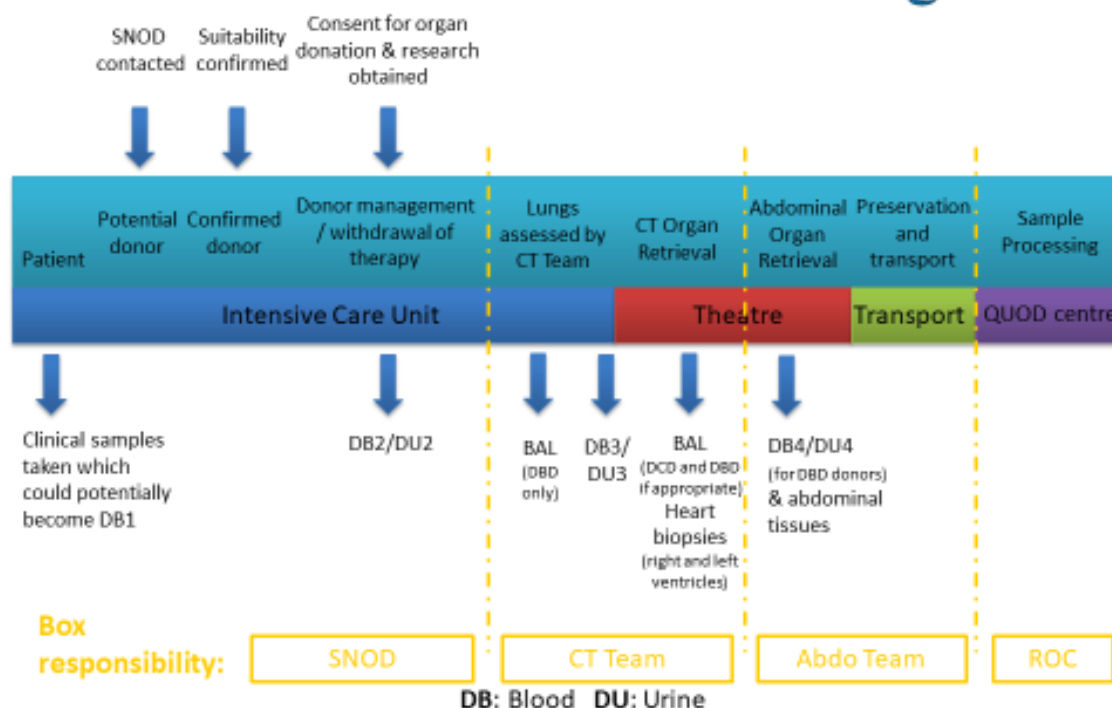
9. Transportation of samples

- 9.1. Check that all tubes (tissues, urine and spleen) have been tightly closed to avoid spillage during transport and make sure the worksheet is added to the box
- 9.2. Ensure replenishment of ice in the ice-box prior to departure
- 9.3. Place the QUOD box inside a large, clear plastic bag to waterproof the exterior and place this upright in the perfusion fluid box. Surround/cover the bagged QUOD box with wet ice to ensure effective cooling in transit
- 9.4. If any spillage/leakage occurs during transportation use a pair of gloves and close the leaking container. Notify the ROC/Lab Liaison on arrival.
- 9.5. On arrival at the QUOD regional lab, remove the QUOD box from the ice and place it in the designated fridge, being careful to keep it upright

All QUOD samples must be obtained from a hospital site that is covered by an extension to the NHSBT HTA licence. NORS teams will take responsibility for transporting the QUOD samples to the designated site (QUOD regional lab) at their base hospital, prior to the samples being transferred within 7 days to the main QUOD lab in Oxford. Responsibility for the samples will then pass to the University of Oxford HTA licence under QUOD Governance

Appendix A: Sample Collection Diagrams

CT Team and Abdo Team attending



Abdo Team only attending

