Document Title: How to use the Tissue Bank Database

Document Number: TB SOP101

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Department:	Research and Development
For use by:	Tissue Bank Staff
Review due:	July 2027

Summary of Amendments

Version Number	Modification:
V1	**Reviewed and updated SOP PRO/AD/TBR/001**

Key Points of this Document

1 Purpose and Contents

a. This document defines the Trust's procedure for using the Tissue Bank database.

b. The Tissue Bank uses a database to record all samples that are stored in the bank or that have been entered on the database and removed for research purposes.

2 Roles & Responsibilities

a. Staff involved in using the database must comply with the requirements set out in Section 4.

b. Training in this procedure will be by a competent member of the RPH research team.

c. Following a period of supervision (depending on the individual needs of the trainee) there will be an informal assessment.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with it may result in disciplinary procedures.

4 Procedure

a. Double click on the Tissue Bank database icon on the desktop. To login, type the password then your username.

4.1 How to search the Database

From the menu page click on search the database.

a. To search using the hospital number only

- Click on the hospital number field and fill in the details.

- Click on search at the bottom of the page.
- Select which tissue or Tissue Bank number you require.
- To view Tissue Bank details, click on edit/view Tissue Bank record.

b. To search using the histopathology surgical number only

- Click on the histopathology number field and fill in the details.
- Click on search at the bottom of the page.
- Select which tissue or Tissue Bank number you require.
- To view Tissue Bank details, click on edit/view Tissue Bank record.

c. To search using the Tissue Bank number only

- Click on the Tissue Bank number field and fill in the details.
- Click on search at the bottom of the page.
- Select which tissue you require.
- To view Tissue Bank details, click on edit/view Tissue Bank record.

d. To Search using the date in or date removed only

- Enter the dates.
- Click on search at the bottom of the page.
- Select which tissue or Tissue Bank number you require.
- To view Tissue Bank details, click on edit/view Tissue Bank record.

e. To search for reserved by or removed for only

- Using the removed for or reserved by drop down boxes, select the appropriate researcher/company.
- Click on search at the bottom of the page.
- Select which tissue or Tissue Bank number you require.
- To view Tissue Bank details, click on edit/view Tissue Bank record.

f. To search using multiple tissue fields

- Highlight the first tissue in your search criteria, then holding down the control button select the rest of the tissues you require in your search.
- Click on search at the bottom of the page.
- To view Tissue Bank details, click on edit/view Tissue Bank record.

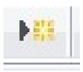
g. To search in text in tissue notes

- Click in the box text in tissue notes and type the free text you wish to search for.
- Click on search at the bottom of the page.
- To view Tissue Bank details, click on edit/view Tissue Bank record.

4.2 TO ADD A NEW USER:

a. Enter the password and press shift and enter at the same time.

b. On tables, double click on tlkpTissueBankStaff.

c. Click on the  button at the bottom; enter the full name, initials and short name. The ShortName will be the person's username. Click on the admin box if this person will be a regular database user.

4.3 BOOKING A SAMPLE ONTO THE TISSUE BANK DATABASE:

a. Double click on the Tissue Bank database icon on the desktop.

b. Logon with password and username. Press ok.

c. Click on 'enter material' or 'Scroll through entries' to allocate a Tissue Bank number.

d. Enter all the relevant patient details in the blank fields e.g., hospital number, date of birth, sex.

e. Enter the tissue acquisition date, and the initials of the pathologist, BMS and TB staff processing the samples.

f. Choose ‘Full’ in the consent box if all the boxes in the Tissue Bank consent form have been initialled including the optional boxes. Choose the ‘No Extra’ button if any of the boxes requesting for extra/additional blood during their routine/subsequent routine care is not initialled. Choose the ‘No Animal’ button if the patient does not consent to using their samples for research that involved animals. ‘No Extra’ and ‘No Animal’ will be selected if both above are not initialled. Fill in the consent date. Write the version number of the consent form on the ‘Version’ field.

g. Enter the number of samples collected in ‘Total Number of Tissue Type Collected’. If the same sample has been collected in more than one tube, enter this as 1 sample at this stage.

h. Follow the specific project forms for the details needed to be entered onto the database.

i. Using the ‘Tissue’ drop-down box select the tissue from the list.

j. Using the drop-down box select the ’Type’ of tissue.

k. When booking blood samples fill in the ‘Vials Received’ with number of vials received.

l. Using the drop-down box select ‘Type II’.

m. If the samples are reserved for a project, fill in the ‘Proj No Reserved’ field using the drop-down box, select the appropriate project number. If the samples are reserved for Tissue Bank or are being removed straight away, leave this field blank.

n. If the same sample has been collected in more than one tube, enter the number of tubes collected in ‘No of Vials’. The appropriate number of boxes will then appear on the ’Location’ tab on the right-hand side for entering storage locations.

o. On the ’Location’ tab on the right-hand side of the screen, put the freezer number, location box/tray, row and position accordingly.

p. Enter the state of the sample using the ‘State’ drop down box.

q. If the samples are being removed straight away, fill in the ‘Proj No Removed’ section using the drop-down box select the appropriate project number.

r. On the ’Summary Info’ tab: Describe the surgical procedure the patient has undergone; enter the procedure specified on the Theatre list if it is a surgical sample.

s. On the ’Questionnaire’ tab, select the relevant questions according to project using the project forms as a guide. Type the answer/information into the ’Comments’ box.

t. To reserve or remove a sample from the Tissue Bank database click on the ‘Location’ tab where all the samples entered will appear. Click on the ‘Choose’ button next to the sample you wish to select, a pop-up box will appear with ‘1 tissue(s) chosen’, press ‘OK’.

u. On the drop-down box for ’Company receiving or reserving tissue’, select the correct company researcher. The ‘Confirm Removal’ and ’Confirm Reservation’ boxes will become active. Click to remove or reserve the samples.

v. This will take you to the next page to confirm what you have selected.

w. If the database is unavailable for any reason, there is a record of samples logged on the Daily sample log excel spreadsheet.

Note: All track and trace sheets will be filed in a folder at the HLRI, scanned and saved in the Tissue Bank files for our records.

4.4 FOR REMOVALS:

The specimen receipt page will open after selecting the confirm removal button. For the purpose of invoicing, fill in all the sections accordingly. Contact person, purchase order numbers are entered in the Agreement No field. Select the project number, shipping company and how packaged using the drop-down list.

a. To return to the database, click on the ’Add-ins’ tab and press back.

b. Some studies or projects request for additional information such as patient status whether living or deceased. This information can be found on the various database systems used by Royal Papworth Hospital. If patient is flagged deceased, type the date on the ‘Date of Death’ field.

4.5 ADDING PARAFFIN BLOCKS TO THE DATABASE:

Using the information on the FRM/TIS/R&D/022- FFPE Block request for RPH Tissue Bank, add the blocks collected from the Addenbrooke’s pathology lab onto the database. This step should be done before the blocks are cut for in-house H&E sections at the section cutting lab.

(Note: If only paraffin blocks have been collected, first follow sections 3.3 A to 3.3 K and then 3.5 C onwards).

a. If you wish to add paraffin blocks to an existing Tissue Bank entry, add the number of paraffin blocks taken to the total number of 'Tissue Types Collected', and press enter.

b. Using the drop-down boxes select the appropriate item.

c. There are two ways to create a paraffin block. On the right-hand side of the page, use the drop-down box or enter the state as Pa' for paraffin. You will notice that the top box corresponding to the paraffin block will disappear, and a new box will appear at the bottom under the heading paraffin blocks.

d. However, if the paraffin block is a parallel tissue to a frozen sample, enter Y to the Paraffin taken box. This will automatically add a paraffin block to the same letter as the frozen sample.

e. Click on the 'Choose' button next to each sample to reserve the paraffin blocks for Tissue Bank or specific researcher. After each selection a prompt box will appear. Click 'OK' and continue until all the required samples are selected.

f. If the samples are being reserved or removed for one researcher, click on 'Select All' to choose all samples.

g. Select Tissue Bank from the drop-down box next to company receiving or reserving tissue at the bottom of the screen.

h. Click the confirm reservation button to complete.

i. A new screen will appear confirming the reservation. Click the add-ins tab and back button to return to the Tissue Bank entry. After the details of the entry have been checked the database may be closed.

4.6 ADDING SLIDES TO THE DATABASE:

Using the information on the FRM/TIS/R&D/027 Section cutting track and trace form, add the slide sections cut from the FFPE blocks. This step should be done after staining and before storing the slides in the blocks/slides. storage units.

a. Paraffin embedded blocks will be sectioned into slides and stained for H&E for Tissue Bank validation or with special stains for specific projects.

b. To add slide samples, click on the 'Slide' button in the paraffin block section. A 'Take slides' prompt box will appear, enter the number of slides you wish to add on the 'Num Slide' field and the type of stain on the 'State' field.

c. Follow step 3.3 M for reservation and step 3.3 Q for removals.

d. When working on a project, we will ask a pathologist to validate the disease on the slide using the HE slides reserved under Tissue Bank. This information should be entered on the 'Note' section at the left side of the screen.

4.7 COMPLETING SUMMARY INFORMATION SECTION:

a. Once the Pathology reports have been authorized on Lorenzo, search the patients' report using their hospital number or NHS number and choose the report that coincides with the date or the 'S' number if you have it.

b. Enter the appropriate sections of the pathology report or summarize with the pathology comment.

c. This information facilitates in searching for diagnosis and disease.

4.8 COMPLETING THE QUESTIONNAIRE

Some projects have specific data required to go with the sample(s). Pick the questions that need to be completed and enter the information gathered from various database systems used by Royal Papworth Hospital.

4.9 USING THE ALERT SECTION

Information typed in this box will appear on both historical and future entries for that hospital number. Use the 'ALERT' box for important information such as Risk of Infection if known and the date the risk was discovered. Also to indicate consent restrictions such as no consent for involvement of animal or DNA/RNA.

4.10 EXPORTING DATA FROM THE TISSUE BANK DATABASE

a. Information from the Tissue Bank database can be exported in an excel format, allowing spreadsheets to be created to provide information on samples collected by Tissue Bank.

b. Using the search function of the database (sections 3.1-3.7) choose the tissue samples required. e.g., to create a spreadsheet of samples reserved for a company during a particular time period, search using reserved by and the date in boxes.

c. After searching the results page will appear with the list of samples.

d. Click on the ‘Excel’ button. This will convert the list of tissues into an excel format.

e. Open Microsoft Excel.

f. On the Tissue Bank database, highlight the whole document and copy and paste the information into the excel spreadsheet.

g. Delete any columns with information not required for the project.

h. Check that the information is correct and is formatted appropriately, before saving the file and closing the program.

4.11 HOW TO RETURN TO STOCK

a. Log into the Tissue Bank database.

b. Choose the removals tab.

c. Type the Tissue Bank number next to the find tab button. DO NOT press enter. Use the drop down to select the specific entry you want to return to stock. Several samples may have been removed to the same researcher, so you need to select the correct removal date.

d. Press ‘return to stock’.

4.12 HOW TO UNRESERVE

a. Log into the Tissue Bank database.

b. Choose the reservation tab.

c. Type the Tissue Bank number next to the find tab button. Do not press enter. Use the drop down to select the specific entry you want unreserved. Several samples may have been reserved to the same researcher, so you need to select the correct reservation date.

d. Press ‘Unreserve’.

4.13 HOW TO ADD A NEW ITEM IN SPECIFIC FIELDS

New Tissue - Follow step 3 and click on the Edit list button, click on the Tissue List, click on the  button at the bottom and enter the tissue name.

New Project - Follow step 3 and click on the Edit list button, click on Projects, click on the  button at the bottom and enter the ‘T0****’ number of the project followed by the researchers name/company in parenthesis.

New Researcher -Follow step 3 and click on Recipients, Companies, Groups button. Click on the  button at the bottom; enter the researcher’s name on the Company/Group/”one off” individual field; the company address; and on the Contacts tab, enter the name of the individual who got in touch with Tissue Bank to collect the sample. You can add several contacts by clicking on the  button at the bottom of the form. To exit the database properly, click on the add-ins tab and press exit.

4.14 HOW TO MASS TRANSFER SAMPLES TO ANOTHER LOCATION

a. Tissue Bank samples are stored in different locations, some in our facility and some are off-site. When a batch of samples needs to be transferred off-site, the actual location should correspond to the information entered in the database.

b. Only trained staff should undertake this task.

4.15 TECHNICAL SUPPORT

The Tissue Bank database is maintained by Pelican Computing. Issues regarding any of the database’s function can be addressed by emailing info@pelicancomputing.com or richard@pelicancomputing.com or by calling Richard Dexter on telephone numbers 01223 329 046 or mobile 07990 598 188.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit.

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2023) Human Tissue Act 2004
Key related documents:	Trust Research Policy Trust Policy DN1 Document Control Procedures **Risk Assessments** RAC/RD/TBR/008- Loss of traceability (Datix 2416) RAC/RD/TBR/005- Labelling samples (Datix 2400) RAC/RD/TBR/029- Tissue Bank Database

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

Review date:	July 2027