Document Title: Tissue Bank (Deposits and Withdrawals)

Document Number: SOP067

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers, Tissue Bank Operational Group
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Directorate:	Research and Development
Department:	Research and Development
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Summary of Amendments

Version No:	Modification:
	Minor modifications to some text for clarification/readability
	Amendment of Figure 1 and removal of Appendix 1
4.0	Addition of the use of Initial Tissue Enquiry form
4.0	Additional detail about Tissue Bank's REC approval
4.0	Process of transferring samples to Tissue Bank from completed REC approved studies
5.0	Minor amendments throughout
6.0	Minor amendments throughout
7.0	

Key Points of this Document

- This document sets out the procedures for Tissue Bank Operational Group review and approval of applications to use human biological materials and/or clinical data acquired via the Tissue Bank for research purposes.
- It provides guidance on the process of applying to the Tissue Bank to either deposit or withdraw biological materials.

1 Purpose and Content

a. This document defines the procedures for ensuring all biological materials available from the Tissue Bank are:

1. Suitably collected, processed and stored in a manner that meets the requirements of the researchers.
2. Only supplied to research projects designed to conform to the requirements of the Human Tissue Act 2004 and subsequent amendments and guidelines.
3. Only supplied to projects conforming to the Research Ethics Committee (REC) conditions of approval for the Research Tissue Bank, which holds generic ethical approval.

For the purposes of the Tissue Bank, human biological materials include blood, sputum, tissues, urine and any other cell containing samples defined as 'relevant material' in section 53 of the Human Tissue Act (2004).

b. Applications to use human biological materials and/or clinical data for research purposes out of the context of the Tissue Bank will be dealt with, as is current practice, through the Research Governance Project Approval System (RGPAS) and reported back to the Research and Development Directorate (RDD) committee (R&D SOP034: Trust Confirmation of Capacity and Capability to Conduct Research Studies).

2 Roles & Responsibilities

a. The Trust has set up a Tissue Bank Operational Group to manage and oversee the use of human biological materials and associated clinical data for research purposes. The R&D Clinical Project Manager with responsibility for Tissue Bank (acting as the Tissue Bank Manager) and Tissue Bank team leader are members of this group.

b. The policy & procedures for the Royal Papworth Hospital Research Tissue Bank are documented in the "Use of Human Biological Materials for Research" document DN361.

c. DN361 includes details of the Tissue Bank regulatory approvals and patient consent procedure; terms of reference for the Tissue Bank Operation Group and links to the latest REC approved versions of the Patient information sheet and Consent form.

d. The Tissue Bank Operational group will regularly review these policies and procedures in the light of new guidance and will operate the Tissue Bank according to current legislation and accreditation, where appropriate, from the Human Tissue Authority.

3 Policy

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

4 Procedure

a. Applications to the Tissue Bank for projects to either deposit or withdraw material follow the same procedure, as outlined in Figure 1.

4.1 Initial review of Application

a. Initial enquiries regarding the availability of specific types of human biological materials available from the tissue bank should be directed to papworth.tissuebank@nhs.net .

The tissue bank staff will liaise with the client and the Papworth Pathologist to ascertain whether suitable materials can be obtained. For the request to proceed the client/researcher must complete a Research Tissue Bank Application Form (FRM043 for tissue or FRM0XX for data only projects).

b. If a client is wishing to store samples with the Tissue Bank the feasibility of the storage requirements will be assessed.

c. If a client/researcher only requires routine clinical data, the availability of the data requested will be assessed.

4.2 Submission of Application

a. The client/researcher should complete the application form and submit this, along with any required supporting documentation, as instructed in the application form.

b. The Tissue Bank Clinical Project Manager, or their delegates, will review the application and supporting documentation to ensure it is a valid application and that it meets research governance requirements for Generic REC approval OR already has project specific Research Ethics Committee approval.

c. Tissue Bank Generic REC approval covers the supply of suitably anonymised human biological material with/without clinical data in the following circumstances, and only if samples are obtained during routine diagnostic procedures, not requiring an additional patient intervention for:

1. Grant-funded research that has been peer reviewed as part of the grant application process.
2. Internally funded research projects or industrial collaborations that have been reviewed and supported by the Research and Development Directorate.
3. Student research projects that are supported by their academic/clinical supervisors and the Tissue Bank Operational Group.
4. To other licensed or ethically approved tissue banks including those within commercial organisations.

d. Project-specific REC approval and project-specific patient consent is required whenever:

1. Collection of human biological materials for research purposes will require an additional patient intervention.
2. Research will produce data likely to be clinically relevant to specific individuals.
3. Research will involve termination of pregnancy or reproductive cloning.
4. Research is considered by either the Tissue Bank Operational group or the HTA designated individual or designated persons to be of a particularly sensitive nature.
5. Research will require human biological materials from under 16 year olds, or from adults without the capacity to consent

4.3 Approval by Tissue Bank Operational Group

a. The project will be reviewed by the Tissue Bank Operational Group (see DN361 policy and procedures document). It will ascertain exactly what resources are required for the proposed research project and what fees should be charged (including storage fees where required).

b. The application form will be updated with relevant feedback by the Tissue Bank R&D administrator and appropriate costs will be added. The form will then be returned to the client/researcher for agreement and signature.

c. If required, a Material Transfer Agreement or Data Sharing Agreement will also be agreed between the Trust and the recipient organisation. This will include details of costs, transfer arrangements and any supporting documentation that has been supplied by the recipient.

4.4 Activation of Project

a. In order to activate the project, the final version of the Tissue Bank application form has to be signed and dated by both the client/researcher and the Tissue Bank Clinical Project Manager and, if required, a fully executed Material Transfer Agreement or Data Sharing Agreement be in place. The Tissue Bank R&D administrator will then email all project related documentation to the Tissue Bank team.

b. The project is now active and Tissue Bank staff will collect/provide human biological materials as agreed. All sample accruals and removals will be documented on the Tissue

c. The Tissue Bank R&D administrator will produce quarterly invoices for recipient organisations based on the samples recorded on the Tissue Bank database, or other arrangements as agreed in individual Material Transfer Agreements.

4.5 Process for transferring of samples in to Tissue Bank following completion of REC approved studies

a. Any remaining samples once a study has been completed where the initial study PIS and consent allow for their use in future ethically approved research, may be transferred into Tissue Bank for storage under the Trust's HTA licence. If the samples are reserved for a research group, there will be a storage fee for this.

b. In order to complete the transfer the Tissue Bank must be supplied with:

1 A copy of the original study PIS (stating the type of research samples may be used for)
2 A copy of all patient consent forms (which must include an option for the use of samples in other ethically approved research).

3 A detailed sample manifest, stating the type of sample and quantity/number of aliquots per donor.
4 Samples in racking/boxes that are easy to cross check with the sample manifest for auditing purposes.
5 A storage history of the samples i.e. have they been thawed and what conditions have they been kept in.

5 Risk Management / Liability / Monitoring & Audit

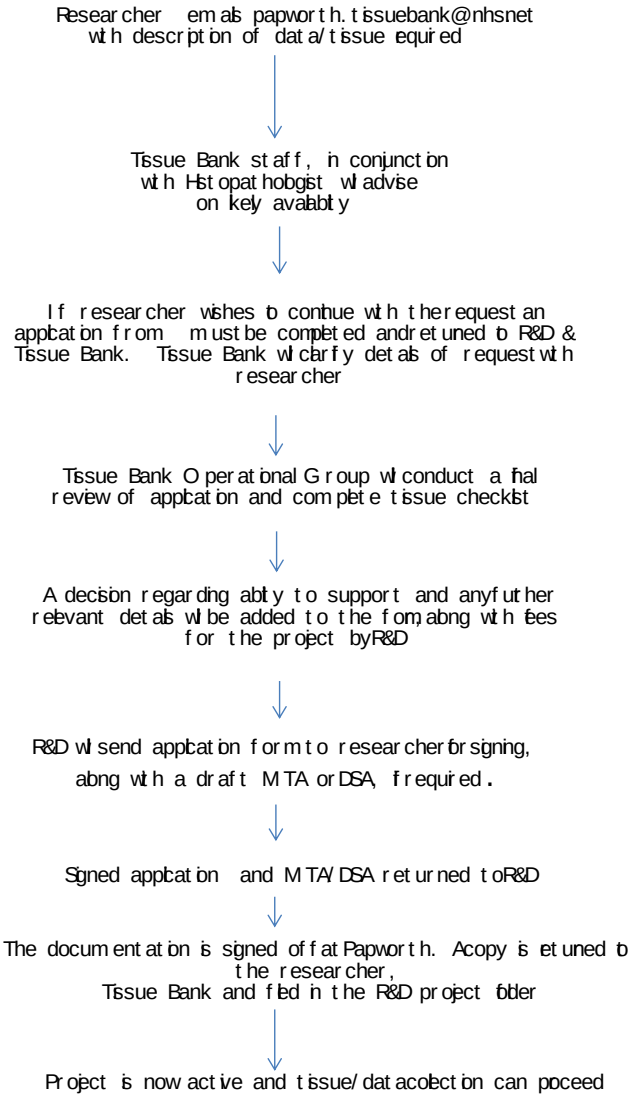
a. The R&D Department will ensure that this SOP, and any future changes to this document, are adequately disseminated.

a. R&D will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (*e.g.* Care Quality Commission, Medicines and Healthcare Regulatory Agency).

b. In exceptional circumstances it might be necessary to deviate from this SOP for which the written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the R&D Master File.

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

Figure 1: Banking/obtaining human biological material from PHRTB



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Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	19th July 2023
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 (2018)
Key related documents:	Trust Policy DN361 Human Biological Materials for Research

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:	

I certify the contents of this SOP has been reviewed and ratified

DocuSigned by: Patrick Calvert 81A52758BFFF421...

Signed by Dr Patrick Calvert, Clinical Director of R&D

06-Sep-2023

Date

SOP release date: .....