Royal Papworth Hospital
NHS Foundation Trust

Document Title: Tissue Bank Project Management

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Staff involved in development: *Job titles only*	Senior R&D Manager, Tissue Bank Team Leader, Tissue Bank Coordinators, Clinical Project Managers.
Document author/owner:	Tissue Bank Team/Senior R&D Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	Tissue Bank Staff
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Summary of Amendments

Version Number	Modification:
V1	**Reviewed and updated SOP PRO/AD/TBR/004**

Key Points of this Document

1 Purpose and Contents

a. This SOP outlines the process for managing Tissue Bank projects, from application through to project closure.

b. The Tissue Bank Operational Group (TBOG) includes members from Research and Development (R&D), a consultant Pathologist (Clinical Lead), Tissue Bank, and Surgical (Theatres). The group meets monthly to review and approve or reject project applications based on ethical considerations, project specifications, and requirements.

c. Each application is assigned a unique identifier: 'T0' for Tissue Bank projects or 'P0' for Portfolio Studies.

d. Project management is conducted by the Tissue Bank team, Research team, and Research Administrator, with pathologist assistance or supervision.

e. The R&D team handles application forms, Material Transfer Agreements (MTAs), costings, and invoicing.

f. Tissue Bank project management is performed by the senior tissue bank team.

2 Roles & Responsibilities

a. Training will be provided by a competent member of the RPH research Tissue Bank team.

b. 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

4.1

a. Application submission

- Initial query received by R&D or the Tissue Bank team.

- The latest Tissue Bank project application form is sent to the applicant for completion.
- Upon return of the completed application, R&D assigns a 'T0' number, files it electronically, and sends a copy to the Tissue Bank/research administrator.

b. Preliminary Review

- Applications are filed by researcher name and 'T0' number.
- Informal review by the Tissue Bank team and research administrator, who complete a TBOG checklist.

c. Database search and consent verification.

- Conduct a database search based on project specifications to find matching samples and diagnoses.
- Verify tissue consent based on extracted database data.

d. TBOG review and costing

- Applications are reviewed at the TBOG meeting, and costings are finalized by R&D.
- R&D provides costing feedback to the researcher and awaits signatures from both parties.
- If required, the MTA is signed by both parties and filed.

e. Project documentation

- Individual project forms are written to guide the Tissue Bank team of project protocols and required database entries.
- Each project is assigned a folder with a status sheet to record actions.

4.2

a. Projects with Prospective Fresh Tissue Collection

- An MTA must be in place before activating tissue collection.
- Label sample containers and media with the 'T0' number and researcher's name.
- Add project details to the Tissue Collection list, divided by organ and disease.
- Tissue Bank team checks daily for sample arrivals and verifies consent.
- Arrange sample banking with the duty pathologist.
- Book samples in the Tissue Bank database.
- Print labels using the zebra printer.
- Inform the researcher of sample collection for pick-up and courier arrangements.
- MTA must be renewed every 5 years for continuous collection.
- Inform the researcher when the sample requirement is met and close the project or amend the application for continuation.

b. Projects with Prospective Frozen Tissue Collection

- Designate and label storage boxes for fluid samples.
- Store frozen tissue alongside the prospective Tissue Bank collection and identify through the database.
- Monitor and inform the researcher once the required number of samples is reached.

c. Projects Requiring Archived Samples

- Perform a search based on project specifications.
- Include pathology reports in the spreadsheet for clinical lead review.
- Insert 'Slide filing location slips' when removing blocks/slides from storage (as per SOP 116)
- Ensure H&E slides are available for validation by the clinical lead.
- Prepare and validate slides, section tissue, and prepare samples for transport.
- Coordinate with the researcher for sample pick-up and courier arrangements.

d. Projects Requiring Data

- Basic data includes demographic and clinical information. Extra data is available at an additional cost.
- Create and complete a data collection template for each project.
- Collect data from the patients Electronic Medical Records.

e. Releasing samples

- A sample release form (SRF) accompanies any sample that is released to researchers. This serves as a sample manifesto that is signed and returned to Tissue Bank
- An outgoing sample log is signed by the courier/researcher picking up the samples.

f. Project Management

- Delegate tasks and report progress during weekly briefings.
- Monthly Tissue Bank Operational Group (TBOG) meetings for project overview and management.

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 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).

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. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

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/029 - How to use the tissue bank database RAC/RD/TBR/030 - Document control **SOP 116 – Blocks and Slides Archiving, Retrieval and Disposal.**

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							

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