Document Title: Blood Banking

Document Number: TB SOP106

Staff involved in development:	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
Review due:	June 2027

Summary of Amendments

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

Key Points of this Document

1 Purpose and Contents

a. This document defines the Trust's procedure for Blood Banking.

b. The document details the requirements for processing bloods.

2 Roles & Responsibilities

a. Staff involved in Blood Banking 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

4.1 Booking in the sample

a. Tissue Bank will be informed by research team collecting the blood that samples are left in the designated Tissue Bank laboratory fridge.

Blood tubes without the patient details (can be LIMS labels/ addressographs or handwritten) will not be accepted and therefore disposed. A member of the tissue bank team will contact the person responsible of the blood collection and will inform them of this disposal.

b. All research samples should have an accompanying Tissue Consent form.

c. Allocate a tissue bank/anonymised number to the samples (refer to SOP101). Individual project form/guidelines will provide the detailed information required to be entered onto the database.

d. Print and collect labels (SOP104 Zebra Printer).

4.2 Protocol

a. Spin any blood samples that require processing in the Tissue Bank laboratory (refer to SOP 096) ensuring that the centrifuge is correctly balanced, and all centrifuge lids are on the buckets correctly. Individual project forms will provide details of spinning times and speeds.

b. Transfer the bloods from centrifuge in the buckets into the hood All research samples should have an accompanying Tissue Consent form.

c. Stick the anonymised labels onto the vials.

d. Set the pipette to the required volume (SOP098), and transfer serum, plasma, cell pellets and whole blood into each of the labelled vials, following the project form guidelines. Repeat until the entire sample has been aliquoted, or the required number of vials has been filled.

e. Dispose of all the used tips into a yellow biobin stored in the hood, then dispose blood tubes in the biobin in the room. Follow Papworth waste disposal procedure DN375 or Medicine Safety Manual for disposals in the HLRI. To clean hood please refer to local policies for operation guidelines. R&D SOP 'Laboratory Biological Safety Cabinet' SOP095.

f. Store the blood tubes at -80oC in the designated R&D Freezer. The samples should be placed in the next available space in the specific storage area. For tissue bank samples indicate the location on the electronic Daily Sample and Tracking Log in Tissue Bank Files

g. For tissue bank samples complete the details of the samples on the tissue bank database (refer to SOP101). Individual project forms will provide the detailed information required to be entered onto the database.

h. Scan the consent form and upload scanned copy to patient's electronic medical records (EMR).

i. Once the consent form has been scanned and uploaded to EMR dispose of the hard copy in the shredding bin.

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 Activity Location Guide **SOPS** SOP104 – Zebra Printer SOP096 – Centrifuges SOP098 – Pipettes SOP095 – Laboratory Biological Safety Cabinet SOP101 – How to use the Tissue Bank Database **COSHH** COSHH/RD/TBR/034 - Tristel Duo COSHH/RD/TBR/035 - Tristel Fuse COSHH/RD/TBR/011 - Alcohol (IDA) **Risk Assessments** RAC/RD/TBR/001 - Blood Collection RAC/RD/TBR/018 - Spillage RAC/RD/TBR/034- Tissue Bank consent and request forms and withdrawal of consent. RAC/RD/TBR/007 - Transport of relevant material RAC/RD/TBR/005 - Labelling samples (Datix 2400) RAC/RD/TBR/003-Collecting liquid nitrogen and freezing samples (Datix 2437)

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:			June 2027				