Document Title: Blocks and Slides Archiving, retrieval and disposal

Document Number: TB SOP116

Staff involved in development:	Senior R&D Manager, Tissue Bank Team Leader, Tissue Bank Coordinators, Clinical Project Managers.
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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/TE/TBR/017**

Key Points of this Document

1 Purpose and Contents

a. This document defines the Trust's procedure for Blocks and Slides Archiving, Retrieval and Disposal.

b. The tissue bank and research team have their own block and slide storage units. See Tissue Bank Activity Location Guide.

c. All tissue bank blocks and slides are stored in numerical order; each drawer is clearly labelled with the range of TB numbers held within.

d. Research blocks and slides are labelled by the specific project number or title and filed in numerical order. On occasions they may be stored in separate drawers clearly labelled.

e. Diagnostic blocks and slides are held on CUH premises for 3 years until transfer to off-site archive at Cellnass.

2 Roles & Responsibilities

a. Staff involved in archiving and retrieving 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 Archiving Blocks & Slides

Tissue bank blocks and slides are filed in numerical case order and alpha-numerical block suffix order (i.e. TB19.0001 A1-A4 followed by TB19.0050 A1-A10). On occasions, and only when a valid tissue bank consent form is in place, tissue bank may use diagnostic blocks for specific projects requesting slides. A tissue bank number is generated by the database for tracking purposes, which will then be linked to the diagnostic block. For a short period, they will be filed numerically in the tissue bank block store until the researcher(s) have confirmed they are happy with sections they have received, and that no more sections are required. Once we have received confirmation that all the sections are received, all diagnostic blocks and slides are to be returned to the diagnostic archive/ laboratory.

4.2 Archived Blocks & Slides retrieval

When blocks and slides are needed for projects, a location slip is completed and placed in the relevant location where blocks and/or slides have been removed from. The location slip should detail Block/Slide numbers removed, interim location, project number (if applicable) and date removed/initials of staff member for traceability.

If diagnostic blocks and slides are required from a Royal Papworth Hospital patient, and where a valid consent is in place, a member of the RPH research team will go over to the Cambridge University Hospitals Pathology archive and retrieve these for subsequent pathologist review and approval for use. Only blocks and slides up to 3 years old are kept on site, older ones are stored at CellNass, Wales.

For CellNass retrievals collate a list of diagnostic case numbers, including the specific suffix number if the whole case isn't required. To order diagnostic blocks and slides from CellNass you must log a request through the CellNass website. Keep a record of the email request for billing purposes, making sure it is clearly labelled with the project number/researcher and date of request.

4.3 Disposal of Research Blocks & Slides

For disposals in Royal Papworth hospital, follow RPH waste disposal policy (DN375). For disposals in the HLRI follow the departmental Medicine Safety Manual. Complete tracking sheets/database to confirm disposal.

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 DN375 – Waste Management Policy **Risk Assessments** RAC/RDTBR/028 – Archiving blocks and slides

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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