Document Title: Retrieval of Blocks and Slides for Clinical Research

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Summary of Amendments

Version Number	Modification:
V1.0	New SOP

Key Related Documents	Trust Policy DN001 Document Control Procedures FRM131 Authorisation for Release of Diagnostic Material for Clinical Research SOP097 Sample Transport SOP111 Microtomy and Section Mounting SOP116 Blocks and Slides, Archiving, Retrieval and Disposal

Key Points of this Document

1 Purpose and Contents

a. Formalin Fixed Paraffin Embedded (FFPE) tissue blocks are widely used for clinical diagnostic purposes.

b. Subject to approval from relevant regulatory authorities and with explicit participant consent (if applicable), FFPE tissue blocks surplus to diagnostic requirement (or material cut from these blocks) may be utilised for clinical research.

c. This document describes the process for retrieval and return of diagnostic blocks and slides for clinical research from the following locations:

1	**Clinical Histopathology Department, Cambridge University Hospitals NHS Foundation Trust (CUH) – STANDARD PROCESS** *Applies where:* • *Tissue processed by CUH Histopathology Dept (Aug 2019 or later)* ***AND*** • *Lab number prefix = PS19, PX19, PS20, PX20, RS20 and onwards, RX20 and onwards*	***See section 4.2***
2	**Clinical Histopathology Department, Cambridge University Hospitals NHS Foundation Trust (CUH) – RESTRICTED PROCESS** *Applies where:* • *Additional approvals and permissions are in place for designated RPH R&D staff to directly access CUH on-site clinical archive*	***See section 4.3***
3	**Off-site archive management service (CellNass)**: *Applies where:* • *Tissue processed by Papworth Hospital Histopathology Dept (Aug 2019 or earlier)* ***AND*** • *Lab number prefix = up to and including 19S*	***See section 4.4***
4	**Other NHS Trusts or private hospital providers** *Applies where:* • *Sponsor requests material for an RPH study participant which was obtained and processed at another hospital site* ***AND*** • *Transfer of relevant material from another hospital location to RPH is solely for research purposes*	***See section 4.5***
5	**RPH-Sponsored study locations (**for use by PTUC only**)** *Applies where:* • *An appropriate MTA is already in place between RPH (PTUC) and participating RPH-Sponsored study locations*	***See section 4.11***

2 Roles & Responsibilities

a. This SOP applies to all personnel that are conducting research at the Trust.

3 Policy

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

b. All movement of slides and blocks (diagnostic and research) must be tracked in accordance with HTA guidelines, Sponsor requirements and R&D SOP097 Sample Transport.

c. Whilst diagnostic slides and blocks from procedures performed at RPH are produced in the Addenbrookes Histopathology Laboratory, RPH remain legal custodian of this material.

d. Release of material for which RPH is legal custodian - for use in research - is at the discretion of an RPH Consultant Histopathologist or authorised delegate

e. Unless otherwise specified, it is assumed that due process has been followed at other NHS Trusts prior to clinical material being released to RPH for use in research, including confirmation that participant consent for release of material is valid. For RPH-Sponsored studies, this process may be subject to audit in line with Good Clinical Practice (GCP).

4 Procedure

4.1 Feasibility

a. During study set-up (and any subsequent modifications), the study protocol and laboratory manual should be reviewed to identify whether provision of blocks and slides is required.

b. Specific protocol requirements should be established at the earliest opportunity and – if applicable - discussed with an RPH Consultant Histopathologist prior to request for local Pathology Directorate Authorisation.

c. Fees for retrieval of blocks and slides and any associated activity should be established and a funding source (usually the relevant study budget) identified.

d. Prior to execution of any Clinical Trial Agreement, protocol requirements and associated costs should be discussed with the RPH Governance team who will advise on contractual arrangements and cost recovery.

4.2 Retrieval and return of blocks and slides *processed by CUH Histopathology:* <u>STANDARD PROCESS</u>

a. Section 4.2 is relevant where tissue from RPH procedures was processed by the CUH Histopathology Department. It applies to cases that remain on-site at CUH, <u>*and*</u> cases transferred by CUH to CellNass for long term storage.

b. All such cases will have a processing date of August 2019 or later and lab numbers will be pre-fixed with one of the following: PS19, PX19, PS20, PX20, RS20 onwards, RX20 onwards.

c. Retrieval and return of blocks and slides for these cases is via CUH Human Research Tissue Bank (HRBT) *following the process described below*:

d. Check that an up-to-date, study-specific RPH Pathology Directorate Authorisation is in place.

e. Check that the study has been registered with the RPH Histopathology Directorate and CUH HRBT (and costs agreed).

f. To register the study (usually done at study set-up), send an email to cuh.tissuebank@nhs.net (cc:phn-tr.papworthpathologyadmin@nhs.net) with the following information:

1. Study full title
2. Study short title
3. IRAS number
4. Principal Investigator name and email address
5. Local research team contact and email address
6. Location address: Research & Development, Royal Papworth Hospital
7. Attach the Participant Information Sheet and blank consent form
8. Attach the IRAS form

g. At time of registration, send a separate email to cuh.tissuebank@nhs.net to request confirmation of up-to-date CUH HRBT fees for retrieval and return of cases e.g. as below (figures from April 2025, example only).

Activity	Retrieving x1 case from archive	Retrieving x5 cases from archive	Retrieving x10 cases from archive	Retrieving x20 cases from archive	Retrieving x30 cases from archive	Retrieving x50 cases from archive	Retrieving x100 cases from archive
Retrieving FFPE slides or blocks from CUH clinical archive	£ 10.57	£ 13.58	£ 17.36	£ 27.92	£ 35.48	£ 49.84	£ 86.84
Returning FFPE blocks and slides to the CUH clinical archive	£ 10.57	£ 13.58	£ 17.36	£ 27.92	£ 35.48	£ 49.84	£ 86.84

h. Note that an administration fee for CUH HRBT database updates may also be charged, fees for commercial and non-commercial trials vary and it is more cost-effective to request retrievals and arrange returns in batches.

i. Once valid directorate authorisation, study registration, costs are confirmed, and relevant regulatory approvals are in place, blocks and slides may be requested.

j. To place request, send a completed CUH HRTB request form along with participant consent form(s) to: cuh.tissuebank@nhs.net (cc: phn-tr.papworthpathologyadmin@nhs.net).

k. Where CUH HRTB need to recall material from CellNass to fulfil a request, additional charges may apply. It is advisable to agree these costs with CUH HRTB prior to them placing the order with CellNass. This should be considered for all cases that were processed more than 3 years ago.

l. Once CUH HRTB have retrieved requested cases, they will arrange for blocks and slides to be reviewed for consideration of release (usually by the RPH reporting Consultant Histopathologist).

m. CUH HRBT will document Consultant Histopathologist authorisation for release of relevant material on their database, as applicable.

n. Once this process is complete, CUH HRBT will contact the requestor to arrange collection from:

CUH Human Research Tissue Bank
1000 Discovery Drive
Level 4, Dame Mary Archer Way
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
CB2 0AX

Tel: 01223 596099

o. If a collection number is provided by CUH HRBT, have this available when attending.

p. CUH HRBT will track released blocks and slides to RPH R&D team on their database.

q. RPH research team will itemise details of blocks and slides received on a study-specific sample tracking spreadsheet.

r. To arrange return of blocks and slides, contact cuh.tissuebank@nhs.net (cc: phn-tr.papworthpathologyadmin@nhs.net).

s. It is advisable to request documented confirmation from CUH HRBT to evidence return of blocks and slides to them. Regardless, ensure local tracking documentation is updated to maintain an auditable record of sample movement and location.

t. Once all relevant material has been released to RPH R&D, CUH HRBT will proceed to invoice for costs incurred (a purchase order may be required).

4.3 Retrieval and return of blocks and slides *processed by CUH Histopathology:* RESTRICTED PROCESS

a. Section 4.3 applies in exceptional circumstances, where:

1. Tissue was processed by CUH Histopathology Dept (Aug 2019 or later) **AND**

2. Lab number prefix is one of the following: PS19, PX19, PS20, PX20, RS20 and onwards, RX20 and onwards **AND**
3. Required material has not yet been transferred to CellNass **AND**
4. Additional approvals and permissions are in place for designated RPH R&D staff to directly access CUH on-site clinical archive

b. Where above criteria are met, direct access to the CUH Histopathology on-site clinical archive for retrieval and return of blocks and slides for research may be considered on a study-by-study basis, subject to approval by Senior RPH R&D team.

c. Where a member of RPH R&D team accesses the CUH archive directly, responsibility for sample tracking, arranging Consultant review of material, ensuring authorisation for release of material is documented and personal compliance with HTA legislation and ICH-GCP lies with that individual. See section 4.6.

d. Any RPH R&D staff granted access to the CUH clinical archive will have a valid honorary contract or letter of access in place and will comply with the conditions stipulated by CUH as part of that agreement.

e. For guidance on relevant roles, responsibilities, training requirements and process related to RPH R&D staff retrieving or re-filing blocks and slides from CUH premises, refer to TB SOP116.

f. Note that (until transfer to CellNass) cases from RS25-1800 onwards are held in the CUH clinical archive at Discovery Drive, rather than in CUH on-site legacy storage space.

4.4 Retrieval and return of *Papworth-processed* blocks and slides from off-site storage with Cellnass

a. Section 4.4 applies to tissue processed by Papworth Hospital Histopathology. Processing date will be August 2019 or earlier and lab number prefix will be up to and including 19S (17S, 18S etc).

b. When groups anticipate regular requests for retrieval of material processed during or prior to August 2019, consider arranging an account and purchase order directly with Cellnass.

c. For occasional retrieval of blocks and slides from Cellnass, the request can be arranged via RPH Tissue Bank (RPH TB). RPH TB agreement for this work and any associated charges is confirmed by Directorate Authorisation. A separate TB request form is not required.

d. Cellnass fees for cost of retrieval, return to archive, shipping and administration will be charged to RPH TB and subsequently reimbursed by requesting team via internal transfer.

e. It is advisable to discuss anticipated Cellnass fees with RPH TB *prior* to Cellnass request being submitted.

f. To request blocks and slides via RPH TB, send a list of diagnostic case numbers (including the specific suffix number if the whole case isn't required) to papworth.tissuebank@nhs.net

g. RPH TB will place retrieval request with Cellnass electronically.

h. Delivery from Cellnass will be to HLRI Goods-In, for the attention of RPH TB.

i. On receipt, RPH TB is responsible for checking that contents of the shipment match the request. The requesting team should be available to assist RPH TB with these checks, if asked.

j. Cellnass will include a receipt for the retrieval charges with the shipment. RPH TB will scan a copy of this into their electronic Cellnass files, noting which project the charges apply to.

k. All material received by RPH TB will be recorded on their master tracking spreadsheet, after which the material can be released to the requesting team.

l. Material released to requesting team should be accompanied by an electronic manifest (may be copied from master tracking spreadsheet) and a copy of the Cellnass receipt.

m. Requesting team will track receipt of material and arrange for Consultant Histopathologist review, as per Section 4.6.

n. To arrange return of unused material to Cellnass, contact papworth.tissuebank@nhs.net who will liaise with phn-tr.papworthpathologyadmin@nhs.net to co-ordinate.

4.5 Retrieval of blocks and slides from other NHS Trusts or private hospital providers

a. On occasion, a Sponsor may request material that was collected and processed at another hospital site (commonly the study participant's local referring hospital).

b. Where transfer of such material from another hospital site to RPH would be solely for research purposes, an appropriate material transfer agreement (MTA) must be in place before blocks and slides are transferred.

c. Where relevant, the MTA may reference explicit consent to exhaust a tumour block (if indicated) and specify whether there is an expectation that non-exhausted blocks will be returned .

d. The process for arranging transfer of surplus diagnostic material from other hospital sites to RPH for research may vary according to local processes. However, in all cases:

1. RPH team will check that study consent permits transfer of surplus material from other sites before initiating request

2. RPH will provide contact at other hospital site with a copy of valid, signed consent form

e. It is assumed that due process will be followed at other hospital sites prior to clinical material being released to RPH for use in research.

f. Shipping arrangements will be study-dependent and as per MTA. As a minimum, RPH will request that the shipment is 'signed for'. Tracked shipment and inclusion of a sample manifest may be preferred.

4.6 Selection and release of blocks and slides for research (*applies where material has been recalled from Cellnass by RPH TB or retrieved directly from CUH archive by RPH R&D staff)*

a. After archived blocks and/or slides have been retrieved directly from the CUH clinical archive by authorised RPH staff, or from CellNass via the RPH TB team, review of the material by an RPH Consultant Histopathologist should be arranged.

b. Unless otherwise specified, review will be carried out by the Consultant Histopathologist who reported the case clinically.

c. Refer to study-specific Directorate Authorisation for details on nature and impact of support agreed from Consultant Histopathologist team.

d. Consider whether there are any key research requirements to highlight to the Consultant Pathologist before any work is undertaken and ensure that they are in receipt of the current protocol and/or lab manual for guidance (as applicable).

e. A copy of a valid, signed consent form must be made available to the RPH Consultant Histopathologist as part of the case review process.

f. The RPH Histopathologist will evaluate material and determine whether it meets Sponsor requirements (e.g. tumour content) and whether it's permissible for the material to be released for clinical research purposes.

g. Where permission is granted, a Release of Diagnostic Material for Research Form (see FRM131) should be completed to evidence the authorisation. The signed form should be filed appropriately with other study documentation and a copy sent to phn-tr.papworthpathologyadmin@nhs.net.

h. A transparent record of cases reviewed / work completed by the Consultant Histopathologist team should be maintained by R&D team member to enable efficient reimbursement of costs incurred by the RPH Histopathology service.

i. Material that is not authorised for release and/or deemed surplus to study requirements will be returned to the relevant storage facility via the route by which it was retrieved.

4.7 Cutting FFPE blocks for research

a. Where slides need to be cut from blocks for research purposes, RPH staff who have completed relevant training and achieved required level of competency are permitted to undertake this task. Refer to Tissue Bank SOP111 Microtomy (Paraffin Blocks & Section Mounting).

4.8 Interim storage of blocks and slides in R&D Department

a. Where short-term interim storage of blocks and slides is required e.g. between retrieval from archive and shipping to Sponsor, they will be stored in a locked cabinet in a secure location.

b. Where RPH R&D block and slide storage units are used, each drawer should be clearly labelled with contents held within (ref: TB SOP 116).

4.9 Shipping samples off-site for research purposes

a. Once appropriate blocks/slides have been identified and authorised for release for research purposes, they can be transferred to the Sponsor or nominated third party as per study protocol/trial agreement.

b. Prior to transfer, ensure that samples are anonymised / labelled as per Sponsor labelling convention and suitably packed. Refer to SOP097 Sample Transport.

c. Local tracking spreadsheets, relevant Sponsor documentation and/or online sample management systems should be updated, and relevant sample management documentation filed in study site file/project specific working folder on shared drive, as appropriate.

4.10 Finance

a. Where applicable, update the EDGE financing tool to ensure that costs associated with provision of blocks/slides to Sponsors are captured for the purpose of invoicing.

b. To arrange a purchase order or manage invoices related to retrieval and return of blocks and slides, usual R&D departmental finance procedures apply.

4.11 ADDITIONAL GUIDANCE FOR CTU STAFF: Transfer of blocks and slides to RPH from locations participating in RPH-Sponsored studies

a. An appropriate MTA to cover transfer of blocks and slides from locations participating in RPH-sponsored studies will form part of trial site agreements.

b. To initiate transfer, RPH Clinical Trials Unit (as Sponsor) will contact locations to request required material.

c. Request to locations will be by email, copying in papworth.tissuebank@nhs.net who provide a sample management service for RPH CTU.

d. When indicated, the request email to locations will include specific instructions e.g minimum tumour content required, request for explicit consent to exhaust block.

e. Participating locations are responsible for ensuring that valid informed consent is in place prior to release of material to RPH. This may be subject to GCP audit by the RPH as Sponsor.

f. Locations will be advised to ship anonymised blocks and slides with a shipping manifest to RPH TB.

g. On receipt, RPH TB will cross-check the shipment and manifest against list of requested material.

h. Prior to accepting blocks/slides, RPH TB require confirmation of participant consent from RPH CTU. If a copy of the consent form from participating location is not available, reasonable alternatives may be considered e.g. a screenshot from Open Clinica showing confirmation from site team that consent is in place and name of person receiving consent.

i. Samples received from other locations for RPH-Sponsored studies are tracked on relevant RPH TB spreadsheet. They do not need to be entered onto the RPH TB database.

j. Once material has been checked and registered with RPH TB, it can be released to RPH CTU (or nominated third party).

k. If there is residual tumour left in a block after research material has been obtained, this may be returned to participating study locations. RPH CTU will be responsible for overseeing return of tissue via RPH TB, as appropriate.

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) (Amendment) Regulations 2025 and any subsequent amendments UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter.

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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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