# Document Title: Research Tissue Bank consent and request forms and withdrawal of consent.

# Document Number: TB SOP103

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| **Staff involved in development:** | Senior R&D Manager, Tissue Bank Team Leader, Tissue Bank Coordinators, Clinical Project Managers. |
| **Document author/owner:** | Tissue Bank Staff/Senior R&D Manager |
| **Directorate:** | Research and Development |
| **Department:** | Research and Development |
| **For use by:** | Research Tissue Bank Staff |
| **Review due:** | September 2028 |



## Summary of Amendments

| Version Number | Modification: |
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| V1 | Reviewed and updated SOP PRO/AD/TBR/007 |
| V2 | Reviewed and updated to include Mesobank Procedure and Procedures to be followed if a patient partially withdraws consent |
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| **Key related documents:** | DN001 Document Control Procedures<br>Activity Location Guide<br>DN361 Biological Materials for Research use Policy<br>DN375 Waste Management Policy<br>DN586 Shredding Procedure<br>Medical Safety Manual<br>SOP101 How to use the Tissue Bank Database |

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| | SOP003 Informed Consent for Research Studies<br>RISK Assessments<br>RAC/RD/TBR/005 - Labelling samples (Datix 2400)<br>RAC/RD/TBR/029 - Tissue bank database<br>RAC/RD/TBR/034 – Tissue Bank Consent and Request Forms and withdrawal of consent. |

**Key Points of this Document**

# 1 Purpose and Contents

a. This document defines the Trust's procedure for Tissue Bank Consent forms and the withdrawal procedure for Tissue Bank and Mesobank.

b. The document details the requirements for the acceptance of a valid, correctly completed Tissue Bank consent form.

# 2 Roles & Responsibilities

a. Staff involved in reviewing consent forms 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 Tissue Bank Procedure

Informed consent, to donate tissue for research, is taken before patients undergo diagnostic procedures. The Tissue Bank consent forms will be collected from RPH by a member of the Tissue Bank team.

## 4.1 Consent forms

a. Check which fields the patient has indicated on the form that they are consenting to. If they have consented to having samples tissue banked, the patient should write their initials in the boxes. The forms should be signed and dated by both the patient and consent taker. If all these conditions are met, tissue bank samples can be collected.

b. The TBOG has agreed that for cases pre-2017 if one date is missing or if the witness and patient's signed dates differ, these forms are acceptable in view of the differing consent processes, within different departments, which were in place at the time. Both patient and witness signatures and initials in the statement boxes must be present. Going forward (2017 onwards) one date is not acceptable. Two different dates can only be accepted if both dates are pre procedure (forms are being posted to the patients in some circumstances and re-discussed on admission which may lead to patients dating the forms pre-admission). Two dates must be present in addition to both signatures and initials in the statement boxes.

c. If there is a sample (tissue or fluid) for banking in the RPH fridge and the tissue consent form is not in the designated pick-up point, check the RPH Patient Records System and the tissue bank scanned folder in Tissue Bank Files by searching the patient's hospital RGM number if a previously scanned copy is available. In this instance, the RGM number can be found on the specimen pots or theatre list. If a consent form cannot be found the sample must not be tissue banked, or if samples have already been taken, these should be disposed of following DN375 or HLRI Medicine Safety Manual if disposing in HLRI.

d. If the patient details, on the specimen pot or blood tubes, do not match the information on the consent form or the patients request form, contact the person sending the samples. If a correct consent is not in place, the person who sent the samples should be contacted to inform them that without a valid consent form tissue bank samples cannot be stored. If a valid consent form cannot be obtained, then the samples must be discarded, and the details recorded in the disposal spreadsheet and Tissue Bank Adverse Event and Near Miss Reporting spreadsheet.

e. Once the consent form is scanned, rename the document with the patient's RGM number, surname and the date the form was consented by the patient. If the form is not valid, include the reason when renaming the document. Save it in the relevant sub-folder in the

scanned folder in tissue bank files. The hard copy can be disposed of in the shredding station for confidential paper provided by the Trust (refer to DN586 for the Trust document shredding procedure).

f. If a consent form is incorrect or incomplete, complete the 'incomplete consent' spreadsheet.

g. A copy of the scanned consent form is also uploaded onto the patient's Electronic Medical Record.

## 4.2 Withdrawal of Consent

Requests for withdrawal of consent should be received in writing. Patients may go through a healthcare professional who will then email the message to us. This request should include enough details to identify the patient (e.g., hospital number and full name). Upon receiving a request:

a. Log onto the tissue bank database and perform a search using the patient's RGM number (refer to SOP101 How to use the Tissue Bank Database).

b. If tissue bank samples have been collected and stored; the samples should be disposed of according to DN375 or HLRI Medical Safety Manual in the HLRI and recorded in the tissue bank sample disposal spreadsheet, with the reason for disposal (e.g., withdrawal of consent). On the tissue bank database, all samples should be marked as 'Disposed', following the protocol for removal of samples, and choosing 'Disposed' as the 'Company receiving or reserving tissue' (SOP101). Remove only the information stored on questionnaire section of the database (e.g., medical history, medication).

c. Samples which have already been anonymized and supplied to a third party cannot be disposed of. The patients are informed of this in the PIS before they sign the consent form.

d. Scan and upload the patient's withdrawal notification and amended version of the consent form, that is clearly indicated with withdrawn consent (score through the consent, mark consent withdrawn, initial and date), to the RPH Patients Record System and the Tissue Banks scanned folder.

e. Delete the original scanned copy of the consent form in the Tissue Bank files and Inform the IT department that the original scanned document needs to be removed off the RPH Patient Records System.

f. If the patient is on a specific trial/research project, the researcher will need to be notified by email to inform them of the patient's request to withdraw consent and that their samples will be disposed of.

### 4.3 Partial Withdrawal of Consent

If the request pertains to a partial withdrawal of consent (e.g., the patient originally consented to optional elements such as animal use or DNA/RNA analysis), a textbox should be added to the original consent form they signed. This box should clearly state: **"I withdraw consent for ……. (state what it is)".**

The amended version of a copy of the original consent form should then be sent to the patient—either via Docusign, email or post—for their signature and date. In the meantime, update the version of the consent form held on file to reflect the partial withdrawal, pending receipt of the signed document. Once the signed form is returned, scan and upload it to the patient's electronic record and the Tissue Bank's scanned folder. Follow step 4.2e to delete original document from Tissue Bank files and patient medical record.

## 5 Mesobank Procedure

a. Informed consent for the donation of tissue for research purposes is obtained prior to patients undergoing any diagnostic procedures.

b. Tissue Collection Centres (TCCs) adhere to their respective local policies for obtaining consent. At RPH, research staff follow the procedures outlined in R&D SOP003: Informed Consent for Research Studies.

### 5.1 Withdrawal of Consent

Requests for the withdrawal of consent must be submitted in writing. These requests may be directed to Mesobank or any of its associated TCCs. The request should include the donor's Donor Code. If the Donor Code is not provided, the relevant TCC should be contacted to obtain it.

TCCs will follow their local procedures for documenting the withdrawal of consent in the patient's healthcare records.

Upon receipt of a withdrawal request, the following steps must be taken:

a. Access the Mesobank database and search for the donor using their Donor Code:

1. Navigate to the 'Donors' page.
2. In the 'Filters' box under 'Find donor by:', enter the Donor Code.
3. Once the donor record appears, check that the Date of Birth, NHS number, and Donor Code match the request.
4. If all details match, click on the blue hyperlinked Donor Code to open the donor record.
5. In the donor record, select the 'Samples' tab at the top of the page.

b. If samples have been collected and stored:

1. Dispose of the samples in accordance with DN375 or the HLRI Medical Safety Manual.
2. Record the disposal in the Mesobank Sample Disposal Record, stating the reason (e.g. "Withdrawal of consent").
3. Disable the corresponding sample records in the Mesobank database:
   - Click on the Disable icon. A 'Disable Sample' dialog box will appear.
   - In the field under 'Enter reason for disable:', input your initials, the reason for disposal (e.g. "patient withdrawal of consent"), and the date of disposal.
   - Tick the checkbox labelled 'Sample was disposed to medical waste'.

   This will update the database to reflect that the sample is no longer held in stock.

c. If samples have already been released to researchers:

1. Contact the researcher by email.
2. Determine whether the samples have already been used.

If used: No further action can be taken.

If unused: Request return of the samples for disposal.

Donors are informed during the consent process that Mesobank cannot retrieve samples or data that have already been used but will request the return of any unused original samples for appropriate disposal.

d. Retain the donor record in the system; however, remove all information stored under the History, Diagnosis and Treatment, and Donor Details tabs.

## 5.2 Partial Withdrawal of Consent

a. The consent forms used for samples collected and stored by the biobank did not include optional clauses. Therefore, if a request is made for a partial withdrawal of consent, the procedure outlined in Section 5.1 (Withdrawal of Consent) must be followed. In such cases, all stored samples must be disposed of accordingly.

## 6 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

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| **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.<br>UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter<br>Human Tissue Act 2004 |
| 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 |
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| **Yes/No** | NO | NO | NO | NO | NO | NO | NO |
| **Positive/Negative** | | | | | | | |
| **Review date** | September 2028 | | | | | | |