The Leeds Teaching Hospitals NHS NHS Trust UNIVERSITY OF LEEDS Standard Operating Procedure	Title	**LTHT / UoL Human Tissue Act (HTA) Standard Operating Procedures applying to the Research Licence** **LTHT Patient Consent Registration via the Patient Registration System (PRS)**				
	Scope	**Details of the procedure for registering consent from LTHT patients onto the Patient Registration System (PRS) for the collection and/or storage of tissues under the LTHT and UoL Human Tissue Authority Research Licence**				
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IMPORTANT NOTE

All non-essential activities related to the collection and storage of human tissues for research were paused in March 2020 due to the Covid-19 pandemic. Essential activities, such as the collection or release of samples for Covid 19 related research or the maintenance of premises or equipment, continued with the appropriate safeguards in place.

The Leeds Teaching Hospitals Trust (LTHT) and the University of Leeds (UoL) are responsible for developing and updating instructions or advice regarding the continuation or resumption of activities within the Trust and University respectively, based on the instructions or advice issued by the relevant public bodies such as the National Institute for Health Protection, the NHS and/or the government. All staff must follow the latest instructions or advice issued by LTHT and/or UoL, depending on the sector within which they work.

The HTA-related activities detailed in this SOP should only be undertaken if:
- they fall within the scope of permissible work according to current LTHT and/or UoL policy;
- the procedures can be adapted to fully observe the current LTHT and/or UoL infection control policy.

The above principles will apply if other exceptional national or local circumstances arise.

Section A LTHT / UoL Standard Operating Procedure

LTHT Patient Consent Registration

1. Consent procedure and confidentiality

1.1 The consenting process is detailed in LRTB SOP D01 (Consenting Procedure for LTHT Patients).

1.2 Staff are advised to familiarize themselves with the requirements for patient confidentiality and data protection by referring to the Leeds Teaching Hospitals Trust (LTHT) policy and procedures and to LRTB SOP M01 (Data Protection and Confidentiality).

2. Process for registering new projects/groups or changes to existing projects/groups in the LTHT Patient Registration System (PRS)

2.1 The Patient Registration System (PRS) is a secure database maintained by LTHT to record patient consent.

2.2 Groups intending to collect tissues for future unspecified research must be supervised by a Person Designated (PD), who is appointed by the Designated Individual (DI).

2.3 New projects/groups can only be added to the PRS following final approval by the DI after the group has demonstrated its ability to ensure compliance with the Human Tissue Act, 2004 (the Act). An action plan will then be agreed with the PRS administrator.

2.4 Any PRS related communication from research groups should be conducted using the PRS administrator e mail address of: leedsth-tr.PRS@nhs.net
The HTA Manager is the substantive PRS administrator, however an alternative PRS administrator is available during long term absences to act on basic change requests such as reactivating passwords. More complex issues / amendments require the return of the substantive PRS administrator.

3. Process for registering users onto the LTHT Patient Registration System (PRS)

3.1 The PRS is only accessible to staff who are employed by LTHT or have an honorary contract with LTHT and work on projects set up in the LTHT / UoL Tissue Tracking System Achiever Medical (Achiever).

3.2 A copy of the PRS user's substantive or honorary contract with LTHT must be forwarded to the PRS administrator. If this is not available, PDs can request the completion of form 'Confirmation of Employment Status'. (See Appendix A)

3.3 The individual member of staff must register for a user name and password (maximum of 10 characters) to access the PRS by completing the User requirements and data requirements sheet (see appendix B). This should be forwarded to the PRS Administrator (currently the HTA Manager).

3.4 The member of staff must provide the relevant information to complete the dropdown fields within the PRS that are required for accurate data collection for their study and must provide updates when appropriate. (See appendix B)

3.5 PDs should give the PRS Administrator written assurance that new users who are also consent takers are appropriately trained in Good Clinical Practice (GCP) in taking consent (as per LRTB SOP D01 Consenting Procedure for LTHT Patients).

3.6 PRS users must be in possession of the correct hardware to allow access to PRS (see Appendix C):
LTHT networked PC, Document Printer, Document Scanner, and Compatible Bar Code Printer with the correct size of label.

3.7 Users must complete PRS training with the PRS administrator, who will sign off the completion of training. New users are issued with the '*Work instructions for users*' document which explains how to use PRS, for example how to print labels, how to change a password etc.

3.8 Any changes to an existing project/group, such as new consent forms or updated ethics reference numbers, must be discussed with the PRS administrator. The PRS Requirements sheet should then be updated using the current version of the sheet (appendix B) and this should be forwarded to the PRS administrator.

4. Process for registering patients and consent episodes onto the LTHT Patient Registration System (PRS)

4.1 PRS users should follow the 'PRS work instructions for use' booklet which is given to them by the PRS Administration during PRS training.

4.2 After the consent has been obtained from the patient and checked for accuracy and completeness, the clinical researcher accesses PRS to identify the patient, via an automatic link to the LTHT Patient Administration System (PAS). The PRS will create a unique patient ID and consent reference, which can only be interpreted by PRS.

4.3 If the patient is not included in the Patient Administration System, the clinical researcher must arrange for the patient to be entered onto it using a minimum of three identifiers, to include the patient's NHS number, where available. The patient can then be registered onto PRS in the usual way.

4.4 In some cases, the patient may have previously made a donation and already be registered in PRS. The clinical researcher must then identify the correct / same patient using at least three identifiers before either:

- creating a new consent episode for that patient, if for a new project.

or

- selecting an existing consent episode, if for a longitudinal study. The same consent form cannot be added again for the same patient.

4.5 Recording of the consent data for the first donation episode is the trigger for the creation of the patient's unique ID.

4.6 In addition to the patient's unique ID, a consent-form-specific reference number will be provided by PRS for each consent form registered for the same patient. This will be based on the relevant consent dropdown field chosen. An example of this number is:

1234A567A (the 9 digit number is a combination of alphanumeric characters. The first 5 digits represent the patient ID and the last 4 digits represent the consent ID. Both are produced by PRS)

4.7 Once the consent data is entered in the required fields, the original, signed consent form containing identifiable data is scanned and the document electronically appended to the consent episode in PRS.

4.8 Once both patient and consent entries have been saved in PRS, the user is unable to amend the entry and should contact the PRS administrator if a required change is then needed.

4.9 PRS removes all patient identifiable data from the consent form and replaces them with the unique ID code, consent reference and barcode. Therefore:

- The patient identifiable data should be contained in a single block on the consent form and written information including signatures must be contained in this defined area.
- The consent forms used must be identical in layout to the master copy originally provided to the PRS administrator for anonymisation to be possible

4.10 An anonymised form is printed ready for the researcher to accompany the tissue samples.

4.11 The clinical researcher may also print multiple labels with barcodes from PRS, containing the Unique ID and consent reference, one of which will be put on the original consent form which is returned to the clinical team for inclusion in the patient's notes as per SOP D03 (alternatively it is possible to print a scanned copy of the original consent along with patient identifiable data and also the PRS patient unique ID and consent reference directly from PRS)

4.12 The remaining printed labels are ready to attach to the sample(s), when collected.

4.13 PRS electronically sends the relevant anonymised patient data and consent data including the patient's unique ID and consent reference, across to Achiever. The clinical researcher must wait for acknowledgement of successful transfer of data to Achiever. If, instead, the system returns an error code, the clinical researcher must contact the Achiever Administrator.

4.14 Once the error code has been resolved, the clinical researcher must contact the PRS Administrator and request for the consent entry to be re imported to Achiever.

4.15 On collection of the sample(s), all patient identifiable data must be permanently removed and replaced with a unique ID code and consent reference bar coded label, already printed from PRS. Any samples too small to accommodate the PRS labels should be sealed in a clear plastic bag and the label attached to the seal of the bag.

4.16 The anonymised sample(s) and anonymised consent form are then handed over to the laboratory based researcher.

4.17 Registering the sample(s) within Achiever is covered in LRTB SOP IT02 (Sample Registration).

4.18 Registering the withdrawal of consent into PRS, where necessary, is covered in LRTB SOP D02 (Withdrawal of Consent by Patients or other Donors).

5. Minimum data required for patient identification

5.1 The NHS number is the key identifier, along with a minimum of two other identifiers.

5.2 In the absence of the NHS number, the full name of the patient, the full date of birth and the address are required to correctly identify a patient.

Appendix A

The Leeds Teaching Hospitals NHS
NHS Trust

Confirmation of employment status at Leeds Teaching Hospitals NHS Trust (LTHT)

It is a requirement under the Research Licence, No 12352, issued by the Human Tissue Authority, to LTHT and on behalf of LTHT and the University of Leeds (UoL) that all HTA relevant research consent episodes are recorded on the IT database entitled 'Patient Registration System' (PRS).

The PRS is an application maintained by LTHT, on the Trust network, and must therefore abide by LTHT information governance / data protection requirements.

All PRS users are appropriately trained by the HTA Manager before access rights are granted. As part of the governance requirements evidence must be provided of either:

- A signed LTHT substantive contract of employment
- A signed LTHT honorary contract (supplementary to the staff members UoL contract of employment)

This proforma may be used to confirm the employment status for those research staff who require access to PRS but are unable (usually due to a long length of service) to obtain a copy of their LTHT substantive contract of employment from HR. It must be completed by their Line Manager / Matron.

Completed forms should be sent to:
Debby Gibson, HTA Manager (Tel: 0113 20 67126)
Risk Management Dept, Basement Level, Trust HQ, St James University Hospital

Or a scanned copy via e mail to debbie.gibson1@nhs.net

About the staff member	
Staff members name requiring PRS access	
Contact tel No	
LTHT e mail address	
LTHT Payroll number	
LTHT network ID	
Employment status (fixed term / permanent)	
Date employment commenced	
Date employment ends	
What is the reason why a copy of the staff members contract could not be obtained	

About the person completing the form	
Name of person completing this proforma	
Designation	
Contact tel No	
LTHT e mail address	
Date of completion of this proforma	
I hereby sign to confirm I have completed this proforma and the above named member of staff is employed by LTHT as detailed above	

Appendix B

Research licence Patient Registration System (PRS) USER and DATA requirements

User detail requirements: This relates to who will actually be inputting the data into PRS and may not necessarily be the consent taker

Name and designation of PRS user / in putter (e.g Research Nurse, Junior doctor)	**Contact details of the user:** (you must provide the Tel No, correspondence address, e mail address)	**Evidence of LTHT substantive or honorary contract provided** (**This must be electronic and paper copy given before user access is given) **State Y / N and contract expiry date in space below**	**Building and room location of identified PC** (this must be exact and include room number and floor level	**IP address of identified PC** (found in top right hand corner of LTHT networked PC)	**LTHT Network login ID of the user** (e.g gibsond This is not the e mail address)

Dropdown data and document requirements: This info will be used to populate the drop down fields

**** Title of consent form** (as you would identify it and therefore the exact title is required as on the consent form itself and the title of the saved document, inc version No)	**Type of project** (Project Specific or Research Tissue Bank)	**** Copy of REC approval letter provided** state Y / N and include the REC reference number and expiry date below	**** Title of Patient Information Sheet** (as you would identify it and therefore the exact title is required as on the PIS itself and the title of the saved document, inc version No)	**Name and designation of the consent taker/s** (e.g Research Nurse, Junior Doctor, Consultant)	**Name of the Person Designated**	**Project Title** (this must be as set up in Achiever) and state below the **Project ID** No as generated by Achiever. (these are what will create the link between the PRS and Achiever)	**Hardware requirements** state Y / N below to confirm you have the appropriate hardware required

**** Please also provide paper and electronic copies of these documents to the HTA Manager (debbie.gibson1@nhs.net Tel: 0113 20 67126)**

Appendix C

Explanatory note for LTHT Patient Registration System (PRS) requirements

PRS:
- Is an LTHT networked system for LTHT patients only
- Must sit on an LTHT networked PC with Windows application
- Can only be accessed by LTHT contracted staff or those with an Honorary Trust contract / Research Passport
- Can only be accessed following successful set up of the project in Medical Achiever, completion of appendix A and following appropriate PRS training

PRS user and dropdown information requirements:
The PRS administrator (currently the HTA Manager for LTHT and UoL) will require user and documentation information in order to set up the relevant project in PRS.

The table of specific requirements needed can be found in Appendix A of LTHT SOP IT01, which should be read in addition to this explanatory note.

PRS hardware requirements:
The following hardware is required for PRS use, although it will depend on local work arrangements as to which configuration is best for the user.
The PRS Administrator can provide suggested hardware on request or provide details of current PRS users for you to establish communication links and possible sharing opportunities between groups.

You will need:

a) LTHT networked PC

b) A4 Document printer (there are no special requirements for this)

c) A4 flat bed scanner. PRS has been programmed to be compatible with and therefore only supports the following scanner:
   - HP Scanjet G4010

d) Bar code label printer
   - The bar code printer must be able to use EPL and ZPL programming commands and be connected via USB cable to the PC. PRS has been programmed to be compatible with and therefore only supports the following 2 printers:
     Zebra LP 2824 plus
     Zebra GX430t
   - PRS will only produce the patient ID / consent reference number and bar code in one size. The bar code printer must be able to print on this size label (see below) and print a standard barcode.

d) Appropriate sized labels:
   - The labels printed for PRS purposes are not required for long term storage as they will only contain patient / consent data and not sample data, therefore standard label quality is sufficient
   - The label must be 30 X 60mm, perforated down the centre, creating two 30 X 30mm printed labels. PRS will produce the unique patient ID and consent reference numbers in written and bar code format on each half.

All new hardware onto LTHT networked PCs can only be installed by LTHT Help desk staff. During this process, you must request Help desk staff to set up the bar code printer to sharing with the title 'PRSBarcode' and the document printer must be the default printer.

Full training will be provided for PRS.

Section B Applicability

1 This SOP is relevant to all staff collecting and storing human tissues relevant to the Act. The list of relevant tissues can be found on the Human Tissue Authority website by following the link:

https://www.hta.gov.uk/sites/default/files/migrated_files/List_of_materials_considered_to_be_relevant_material_under_the_Human_Tissue_Act_2004.pdf

2 This SOP can also be used as a training tool for new members of staff who have never worked with human tissues before, or who need to follow a new process.

3 This SOP has been written to formally establish a consistent procedure for the registration of patient consent in the LTHT consent registration system in the context of 1.1.

4 The main aim of this SOP is to ensure that relevant staff, by referencing this document, can easily follow the process of registering patient consent and obtaining a unique identifier from the secure LTHT database to allow pseudonymisation of samples.

Section C Background

1 Different sample types (blood or other bodily fluids, surgical resections etc) and data are collected from patients and other donors in Leeds for future unspecified research into a wide range of conditions including the investigation of normal cellular functions and their disruption in disease states, whether cancer or non-cancer. The tissue collections resulting from these different research activities are grouped under one research licence granted by the Human Tissue Authority to cover both Leeds Teaching Hospitals NHS Trust and the University of Leeds and referred to as the Leeds Research Tissue Banks. However, not all of these tissues are held within an NHS Research Ethical Committee approved research tissue bank.

2 The Leeds Teaching Hospitals NHS Trust is registered as the Licence Holder with the HT Authority, and the principal licensed site ('the hub') is St James's University Hospital. The University of Leeds main campus and Chapel Allerton Hospital are named satellites on the licence.

3 The research licence **does not** cover all areas within St James's University Hospital, the University of Leeds main campus or Chapel Allerton Hospital, but only named research groups and premises within those sites. There is a formal Leeds HT Act governance structure as described below.

4 The Licence Holder is responsible for appointing a suitable Designated Individual.

5 The DI plays a key role in implementing the requirements of the HT Act as the person under whose supervision the licensed activity is authorised to be carried out. The DI has the primary (legal) responsibility under Section 18 of the HT Act to secure that:

5.1 Suitable practices are used in undertaking the licensed activity;

5.2 Other persons, such as the Persons Designated (PDs), working under the license are suitable and;

5.3 The conditions of the licence are complied with.

6 The Persons Designated are charged with adapting the overarching HT Act related SOPs, including this one, into local SOPs to reflect local conditions and research pathways. They are also responsible for the supervision of staff working to HT Act standards (more detail is available in a separate document "Role of the Person Designated).

7 The organisational chart for the research licence, with details of key personnel responsible for specific HT Act activities, is routinely updated by the HT Act manager and any changes are submitted to the HT Authority.

8 The HT Authority determines the timing and frequency of inspection of an organisation holding a research licence based on a risk assessment. All areas listed in the organisational chart are subject to inspection.

Section D Definitions

The Act	The Human Tissue Act, 2004
DI	Designated Individual as defined by the Human Tissue Authority
HT	The Human Tissue Authority or Act
LTHT	Leeds Teaching Hospitals NHS Trust
PD	Person Designated as defined by the Human Tissue Authority
R&I	Research & Innovation
SOP	Standard Operating Procedure
UoL	University of Leeds

Section E References

Human Tissue Act, 2004

Human tissue Authority, Codes of Practice 2017

Code A: Guiding principles and the fundamental principle of consent
Code E: Research
Code E: Research standards and guidance

Joint Policy for the Storage and Use of Human Tissue – a collaborative document agreed by Leeds Teaching Hospitals NHS Trust

Section F SOP details and approval process

Previous Author: Debby Gibson, HTA Manager

Reviewer: Patricia Harnden, DI

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