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**				
	Scope	**Details of the procedure for consenting LTHT patients for the collection and/or storage of tissues under the LTHT and UoL Human Tissue Authority Research Licence**				
	Version	**5.0**	Date issued	**June 2022**	SOP ID	**LRTB SOP D01**
	Planned Review date			June 2024		

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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

Consenting Process for LTHT patients

1.0 Staff

1.1 The process of consent and all handling of patient identifiable material will be undertaken by Trust staff or staff with an honorary Trust contract.

1.2 Staff are bound by the LTHT policies on patient confidentiality and data protection, and must be familiar with the policies as they apply to tissue collection as per SOP LRTB M01 (Data protection and confidentiality).

1.3 If the member of staff obtaining consent is not a member of the patient's clinical management team, such as a research nurse, the clinical team should ask the patient for permission to involve the research nurse or other consent taker in the consenting process. This dialogue must be recorded in the patient's case notes by the clinical team or by use of a signed permission to approach form which must be stored in the patient's case notes (see 6.0).

1. 4 All staff undertaking consent must be trained in Good Clinical Practice (GCP) and such training must be documented as per SOP LRTB M04 (Training).

2.1 Consent Pathways

2.1 Given the necessarily wide range of clinical care pathways, there will be local variation in the consent pathway depending on the types of clinical procedures and the organization and timings of local clinics and/or admissions procedures.

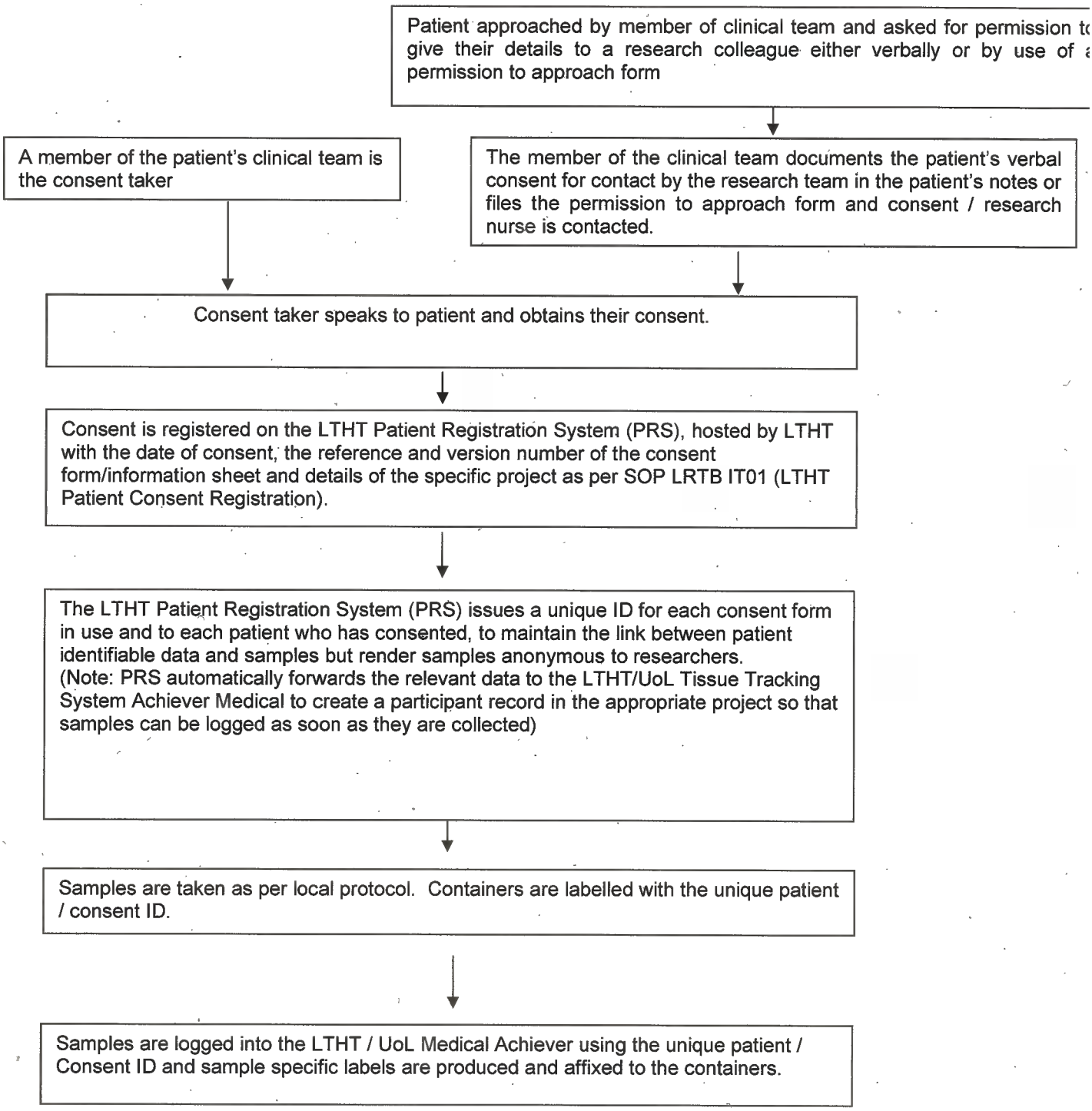
2.2 Some groups may have other consent pathways for non LTHT donors' in place. These are not currently covered in this SOP.

2.3 The general information required to document the consent pathway is shown in section 2.5.

2.3 The specific consent pathway and names, designation and contact details of those involved in the different stages of the process must be documented and kept in a site file by the local Person Designated (PD) or their delegate (eg RTB manager).

2.4 Any changes to the consent pathway must be reflected in the flow charts.

2.5 GENERAL CONSENT PATHWAY



3.0 Donated Tissues

3.1 Different research applications require different tissue types, and the details of their collection must be documented as a flow chart of the specific pathway within the site file of each research group.

3.2 Donated tissues may be split into different samples following processing. Each of these "daughter" samples will be assigned a unique sample code by Achiever Medical to ensure traceability of all daughter samples back to the original tissue donation and thereby to the patient's consent.

4. 0 Responsibilities of person taking consent

4.1 A checklist for consent is detailed on the next page as an aide-memoire for the individual taking consent to ensure that all points are covered during the patient interview.

4.2 The individual obtaining consent should ensure that:

4.2.1 If appropriate, a member of the clinical team has determined whether the patient can be approached for consent, has had a preliminary discussion with the patient and documented their consent to be approached or obtained a signed "permission to approach" form (applies only if the individual taking consent is not a member of the relevant clinical team). No action should be taken before this has been done.

4.2.2 The patient fully understands the information sheets before consenting and has had the opportunity to ask any additional questions.

4.2.3 The patient has printed their forename and surname and signed the consent form.

4.2.4 If the patient is unable to sign the consent form, that the reason for this, for instance visual impairment, is recorded on the form.

4.2.5 If 4.2.4 applies, the forename and surname of the patient's nominated representative is printed on the form, the relationship to the patient recorded and the consent form signed.

4.2.6 Patient consent is recorded on the LTHT Patient Registration System (PRS), as per SOP LRTB IT01 (LTHT Patient Consent Registration).

4.2.7 Any deviations, such as in 4.2.4 and 4.2.5, are recorded in the relevant consent folder's notes field of PRS.

4.2.8 Documentation is completed and stored as per SOP LRTB D03 (Patient or Donor Documentation).

4.2.9 Theatre, pathology or other relevant staff are notified and tissue collection is organised.

4.2.10 All samples are labelled with the PRS unique patient / consent ID.

4.2.11 Samples are processed according to local protocol. Any deviation to sample procurement protocols is recorded by the person responsible for the change against the relevant sample(s).

4.2.12 The consenting pathways are kept current and any deviation to the consent process is reported to the PD, who should investigate and inform the DI/HTA manager.

4.2.12 All samples generated from the original tissue donation are coded and stored using Achiever Medical.

5.0 Informed Consent Checklist

Items that must be explained and discussed with the donor during the interview:

Personal introduction, job description and how may be contacted.	☐
Tissue for donation when taken as part of a diagnostic or therapeutic procedure is surplus to diagnostic or other clinical requirements.	☐
Consent for additional samples (note number and type).	☐
No aspect of their treatment is affected by donation (or non-donation).	☐
Donation is not obligatory.	☐
Donation is confidential (as is non-donation).	
Tissue donated remains linked to the patient's consent but is anonymised to the researchers. There will be no direct contact from the research group.	☐
Relevant medical information will be stored in a secure database and only passed on to the recipients of tissue in an anonymised form.	☐
There is no financial inducement to patient, researcher or clinician.	☐
Tissue is not sold but costs may be recovered.	☐
Tissues may be used in both commercial and non commercial research.	☐
Researchers or their organizations may apply for patents for any treatment or diagnostic test successfully developed from the research and could potentially make a profit.	☐
Benefits to patients are humanitarian rather than personal	☐
Patient has been given an information leaflet.	☐
The process for withdrawal of consent has been explained.	☐
Patient has printed their forename and surname and signed the consent form.	☐
If the patient is unable to sign the consent form because of visual or any other impairment, the forename and surname of their nominated representative, and their relationship to the patient is recorded and the consent form is signed	☐

Comments/observations

6.0 Permission to approach form

Dr/Mr/s ..... a member of my clinical team, has explained that I could be invited to contribute to medical research. I am happy for a research nurse to approach me to explain this in detail, so that I can decide whether or not I want to participate.

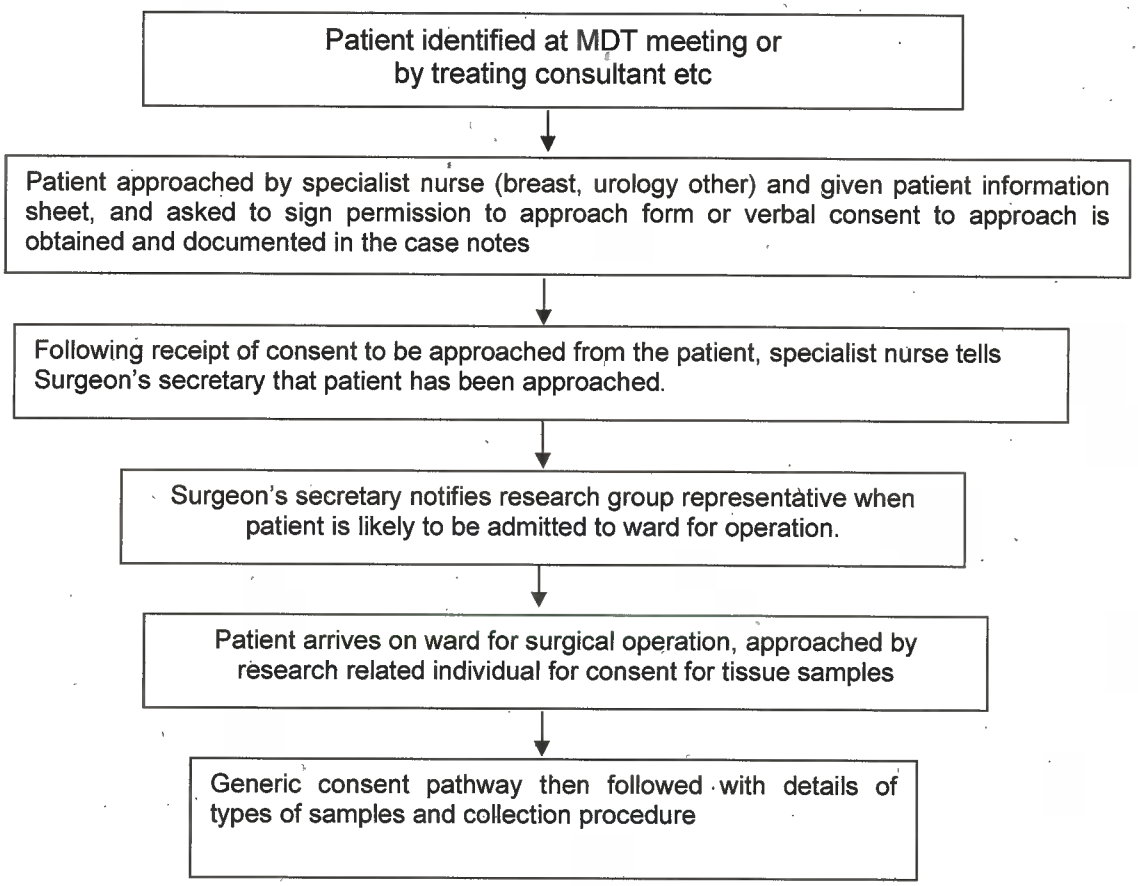
Patient name: .....

Signature: .....

Date: .....

7.0 Tumour and site specific pathways

Examples of a possible pathway



Section C Applicability

1.1 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/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004/list-materials

1.2 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.

1.3 This SOP has been written to formally establish a consistent procedure for the process of consent for LTHT patients.

1.3 The main aim of this SOP is to ensure that relevant staff, by referencing this document, can easily follow the process of consent for LTHT patients.

Section D Background

1.1 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.

1.2 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.

1.3 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.

1.4 The Licence Holder is responsible for appointing a suitable Designated Individual (DI).

1.5 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:

1.5.1 suitable practices are used in undertaking the licensed activity;
1.5.2 other persons, such as the Persons Designated (PDs), working under the license are suitable and;
1.5.3 the conditions of the licence are complied with.

1.6 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).

1.7 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.

1.8 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

B SOP details and approval process

Previous Author:	Patricia Harnden, Designated Individual for the Research Licence
Reviewer:	Patricia Harnden, former Designated Individual for the Research Licence Clare Skinner, new Designated Individual for the Research Licence
SOP Pages:	10
Version No. of replaced SOP:	4
Effective date of replaced SOP:	17th June 2022
Review date for updated SOP:	Biennially from date of approval or review
	Review Date: By:

Review and Approval Process:

Draft	Circulated to	Period of circulation (dates)	Comments received from
Version 0.1	All Persons Designated and key associated staff, HTA Manager, LTHT and UoL Research and Innovation, Medical Achiever leaders	8th September 2020 to 9th October 2020	Debby Gibson, Sarah Myers, Ann Morgan

Version No of the SOP	Name of DI	Date	Signature
5.0	Mrs Clare Skinner Designated Individual LTHT/UoL Human Tissue Act	17/06/'22	Clare E

Distribution & Storage:

Distribution to

Persons Designated, LTHT/UoL HTA Research Licence, HTA Research Subgroup

Location of Document

Paper: HTA Manager, Risk Management, The Trust Headquarters, St James's University Hospital

Electronic: https://ris.leeds.ac.uk/research-ethics-and-integrity/other-resources/research-involving-human-tissue/