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** **Managing Human Tissue Samples in Achiever Medical**				
	Scope	**Details of the procedure for creating and managing HTA research tissue banks in Achiever Medical under the LTHT and UoL Human Tissue Authority Research Licence**				
	Version	**V2.0**	Date issued	**2021**	SOP ID	**LRTB SOP IT02**
	Planned Review date			2023		

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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

Managing samples in Achiever Medical

1. Purpose

1.1 Achiever is the LTHT/UoL Tissue Traceablity System to ensure compliance with the HTA Traceability Standard.
1.2 The Traceability Standard mandates the maintenance of a complete record linking donor consent with the precise location and fate of all their samples.
1.3 Regular tissue traceability audits are mandated to document compliance.

2. Person and Equipment Requirements

2.1 The person requiring access to Achiever must have a substantive or honorary contract with either Leeds Teaching Hospital Trust (LTHT) or the University of Leeds (UoL)

2.2 The user must have a PC with a LTHT or UoL network connection and a screen with a minimum resolution of 1024x768.

2.3 The PC must be installed with Internet Explorer 11, Google Chrome or Mozilla Firefox and Microsoft Office 2013 or later.

2.4 To obtain access to Achiever, staff must have a UoL or LTHT computer account and agreed to the terms and conditions of the relevant organisation and its security policy.

2.5 It is the responsibility of the employing organisation to authorise and issue a computer account.

3. Types of Users

3.1 The use of Achiever is mandated for the storage and management of HTA relevant material.

3.2 Achiever may be available to use for any project with NHS Research Ethics Committee (REC) project specific approval following discussion with the HTA management team lead by the Designated Individual (DI). Users must accept that any changes to the functionality of Achiever can only be made following a review process that ensure the primary purpose of Achiever to ensure compliance is not compromised.
3.3 Existing holdings (tissues collected prior to September 2006) will also be recorded in Achiever.

3.4 HTA relevant samples may be held within an NHS REC approved Research Tissue Bank (RTB) if the donors are primarily NHS patients. However, some research groups will only work with HTA relevant samples from healthy volunteers or other non NHS sources.

4. Research Group Requirements

4.1 A Person Designated (PD) within the HTA governance framework is the member of staff who has been selected by the DI and is responsible for assisting the DI in developing and implementing the required procedures to ensure compliance in their local area. The PD will be responsible for oversight of the local project(s) within Achiever.

4.2 In addition, each research group will need;
4.2.1 A team administrator who will be responsible for overall administration of the project(s).

4.2.2 If any members of a project team require access to patient identifiable data, a Security Officer must be appointed. The Security Officer will have responsibility for determining whether individual users can see patient identifiable data or not. If a Security Officer is not assigned to a research group's Achiever project, no members of the project team will be able to view patient identifiable data.

4.2.3 The above three roles should normally be undertaken by different individuals to ensure that there are checks and balances.

5. Information Required for Achiever

4.1 A holding is created as a ` project' within Achiever.

4.2 Instructions on how to create a project in Achiever are in User Guide 1-01 LTHT Setting Up Projects.doc available from the Research and Innovation website.

4.3 The creation of an NHS REC approved RTB project requires:
- 4.3.1 A title that matches the title approved by the REC.
- 4.3.2 The REC approval reference.
- 4.3.3 Selection of `HTA Research Tissue Bank' as project type.
- 4.3.4 The name of a Chief Investigator
- 4.3.5 The name of a Security Officer (if required).
- 4.3.6 The name of the Oversight Officer (the Person Designated).
- 4.3.7 Selection of the Start/End dates which are the start and end dates set by HRA NRES in the Ethics Approval. This automatically turns on the "Active" status, a non-editable tick box. Once the end date passes, the 'Active' flag shows as unticked until such time as the end date is altered e.g. once a new Ethics approval has been arranged.
- 4.3.8 Tissue Return date – the end date set by HRA NRES

6. Donors and consent

5.1 A person donating tissue within Achiever is known as a Tissue Donor.

5.2 A Tissue Donor may donate tissue to more than one Achiever project and will therefore have a separate Participant record within each project with an appropriate consent record.

5.3 Tissue Donor, project participants and consent records for LTHT patients donating tissues to HTA Research Tissue Banks will be created in the LTHT PRS system (see **LRTB SOP IT01**) which will then create an equivalent record in Achiever. In this instance, the Tissue Donor is only identifiable by the Achiever Donor Reference, which is the same as the PRS reference.

5.4 For non-LTHT donors or LTHT patients donating tissues to non-HTA projects, the tissue donor, project participant and consent record must be created manually in Achiever.

5.5 For donors created directly in Achiever, sufficient information must be recorded to allow for the individual donor to be identified. This does not need to be commonly used personally identifiable information such as name, address etc, but may be an identifier which can be linked back -to a record stored externally to Achiever which contains the personally identifiable information by staff with the appropriate permissions.

5.6 Identifiable information is encrypted within Achiever and only visible to users who have been authorised by the project security officer.

5.7 The consent record must include the name of the consent form used, the date taken, the consent taker and the location of the actual consent form (case notes is acceptable). A copy of the consent form can be linked to the consent record but must be anonymised.

5.8 Instructions on how to create participants, donors and consent are in User Guides 1-02 LTHT Adding New Donors and Linking to a Project.doc and 1-03 LTHT Adding Existing Donors as Participants (see 4.1).

7. Storing Tissue Samples

6.1 Each storage unit (cupboard or freezer) used for tissue storage under the HTA research licence must be included in Achiever Medical to allow each tissue sample to be located at all times.

6.2 Achiever storage records must match the record in the inventory specified in **LRTB SOP M05** (Equipment use, maintenance and failure contingency).

6.3 Achiever storage location must include the type (e.g. -80 freezer, -20 Freezer, Dewar, Fridge, Cupboard etc), the location or address (site) and a responsible person.

6.4 Tissue must be recorded in Achiever by the storage location and sub location (shelf, box, column, row etc.). Use of the Achiever place number is not mandated providing the tissue sample can be easily located within the storage location/sub-location.

6.5 Tissue not located in a storage location must be checked out using the appropriate Achiever workflow to a named individual. This can be an Achiever user, a member of the University or LTHT who is not an Achiever user or a person at an external instititution.

6.6 When changes to tissue location are made, a reason is entered by the user, and the date, time and name of the person actioning the move is logged by the system.

6.7 Instructions on how to create and manage storage within Achiever are in User Guides 1-11 LTHT Setting Up Storage Management.doc, 1-12 LTHT Linking Storage Locations to Projects.doc, 1-13 LTHT Monitoring Storage Location Environment History.doc, 1-14 LTHT Managing Storage Location Capacity.doc. (see 4.1).

8. Registering and processing Tissue Samples

7.1 All samples must be registered to a donor/participant with an appropriate consent record in Achiever except if:

7.1.1 A project has tissue through an approved tissue transfer agreement with another institution which holds the consent record. In this instance, the donor/participant must be created for Institution providing the tissue, the TTA is held as linked document. A consent record should be created stating that consent is held at the host institution.

7.1.2 As an exceptional event, a sample is held temporarily within Achiever whilst the appropriate donor/participant/consent record is sought. A regular review of samples without consent will be made on a monthly basis by the Application Support team and a report listing any such samples will be sent to the Person Designated and the HTA research subgroup. Samples held without consent must not be used in research. A note should be made in Achiever against the sample explaining why consent is pending.

7.2 Tissue samples can be split into constituent samples in which case a full family history of the sample is retained. Constituent samples retain their link to the Donor/Participant and consent record.

7.3 A tissue sample record can be closed or ended in Achiever in one of three ways:

7.3.1 If a tissue sample is used up or entirely split into separate samples for research, it is marked as depleted.

7.3.2 If a tissue sample is disposed of (as specified in LRTB SOP M06 Disposal of Human Tissue) it is marked as destroyed. A reason for disposal must be entered.

In both of the above cases, the record of the tissue is retained but no further actions can be taken within the system.

7.3.3. The record of a tissue sample can only be deleted if it has been created by mistake or has been created s a 'ghost' record to allow research groups to pre-generate labels for printing prior to sample collection. If a sample record is deleted, a record of the sample record is retained for audit purposes but is not visible to system.

7.4 Tissue splitting, depletion, disposal and deletion are recorded by date/time and person taking the action.

7.5 Instructions on registering and processing samples within Achiever are given in User Guide 2-04 LTHT Adding Samples against Participants.doc, 2-05 LTHT Checking Out Samples.doc, 2-06 LTHT Splitting Samples.doc, 2-07 LTHT Making Sample Requests.doc, 2-08 LTHT Marking Samples as Depleted.doc (see 4.1).

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:
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm

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.

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 Trust. The University of Leeds main campus and Chapel Allerton Hospital are named satellites on the licence.

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

1.4 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:

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

1.2 This SOP has been written to formally establish a consistent procedure for the registration of samples within the LTHT / UoL Laboratory Management and Tissue Tracking System (Medical Achiever).

1.3 The main aim of this SOP is to ensure that relevant staff, by referencing this document, can easily follow the process of registering samples, obtaining a unique sample identifier and tracing

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
Details:

Previous Author: Sarah Jacques

Reviewer: Patricia Harnden, Designated Individual for the Research Licence, Chris Chambers, Achiever IT manager

SOP Pages:

Version No. of replaced SOP: V1.0

Effective date of replaced SOP:

Review date for updated SOP: Biennially from date of approval or review

Review Date: By:
Review Date: By

Review and Approval Process:

	Circulated to	Period of circulation (dates)	Comments received from
Version 2, draft 1	Chris Chambers, Liam Draper	Comments received on 27/03/2020	Chris Chambers, removal of unnecessary items and minor corrections
	Lockdown took place immediately after all changes were agreed and with most staff on furlough, the draft was not circulated. It was not circulated later due to an oversight. However, the changes that were made were minor and mainly to do with re-formatting and updating some designations. As the DI who had overseen the revision was leaving on 31/12/2021, the decision was made to publish the SOP and alert the new DI.		

Version No of the SOP	Name of DI	Date	Signature
2.0	Dr Patricia Harnden Designated Individual LTHT/UoL Human Tissue Act	23/12/2021	

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: Research and Innovation website, UoL., http://ris.leeds.ac.uk/info/72/relevant_legislation/107/hta/2