Human Tissue in Research

HTA-CORE-SOP– Chain of Custody

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the requirements for tracking the movement of human tissue between departments, sites and organizations.

All individual human tissue samples must be uniquely labelled and tracked from the point of collection to disposal. Records of sample traceability, including transfer, use, storage and disposal must be maintained.

An inventory of samples held under a licence must be submitted to the Human Tissue Governance Officer (HTGO) upon request for internal audit or external audit by the Human Tissue Authority (HTA). Failure to maintain accurate records may lead to the HTA revoking the university's research licence and may have legal consequences.

2. Scope

This SOP applies to all SU staff and students involved in research projects intending to use human tissue considered relevant material under the Human Tissue Act 2004 (HT Act). However, it can be applied to any type of human tissue sample, including material that is not considered relevant under the HT Act such as human DNA and RNA, acellular human biological fluid and human-derived cell lines.

All human tissue samples should be traceable from the point of collection through to the point of disposal. Whilst there are software and paper-based solutions for tracking samples once they have been received in a laboratory, there is also a requirement to track the movement of tissue between separate physical locations even within the same laboratory. This SOP and Tissue Transfer Record should be used alongside laboratory sample tracking solutions (paper or software-based) where software solutions do not have the functionality to track tissue samples before they arrive in the laboratory.

3. Roles and Responsibilities

The HTA requires that the Designated Individual (DI) be responsible for ensuring that appropriate procedures and practices are in place to facilitate the traceability of human tissue during transfer/transportation.

The Person(s) Designated (PDs) carry the role of supporting other staff and students, within their local areas, to comply with the HTAct including accurate sample tracking.

The Principal Investigator (PI) responsible for a tissue collection must ensure their research group implement a tissue tracking system.

The HTA Governance Officer is responsible for ensuring that this SOP remains fit for purpose.

4. Procedure

- Unless specific consent is in place to transfer patient identifiable information, tissue samples should be assigned a unique identifier at the point of donation for purposes of anonymisation.

- Each tissue type, even if originating from the same donor/participant should be allocated an anonymised & unique identifier.

- Multiple aliquots of a single sample should also be labelled with unique identifiers. E.g. 10ml of blood from donor 1 is aliquoted into 10 smaller receptacles; each receptacle must have a unique identifier which links them back to Donor 1.

The use of Excel or similar spreadsheet tools can be used to maintain an accurate sample log, however, there are several specialised software for sample tracking available e.g. LabCup, LabKey, & QuartzBio.

Example unique identifier format:

Anonymised donor number - Initials of Researcher - Sample type – Aliquot number

01-HT-blood-1

The above example format can be tailored to your study, the aliquot number could be replaced with the sample collection date if the same donor provides more than one sample. A study reference could be included if needed.

Anonymised donor number	**Initials of Researcher**	**Tissue Type**	**Aliquot**		**Sample Unique ID**
01	HT	PBMC	1	=	01-HT-PBMC-1
01	HT	PBMC	2	=	01-HT-PBMC-2
01	HT	PBMC	3	=	01-HT-PBMC-3
01	SJ	Plasma	1	=	01-SJ-Pl-1
01	SJ	Plasma	2	=	01-SJ-Pl-2
01	SJ	Plasma	3	=	01-SJ-Pl-3

- Details of all sample types, unique identifiers and despatching and receiving personnel should be logged at the location of tissue collection, upon dispatch and on arrival at the destination. Please utilise the HTA-FORM-Tissue Transfer Record to facilitate this.

- A fully signed copy of the HTA-FORM-Tissue Transfer Record must be retained by the PI with the study/collection/biobank documentation of both the Provider and Recipient and made available upon request for internal or external audit.

- If a courier is used, all tracking documentation should be retained by the PI and must be presented for internal and external inspections.
- Guidance for the transportation of human tissue can be found in HTA-CORE-SOP-Transportation.

- All aspects of human tissue handling, including tissue traceability should be risk-assessed by the research team in line with HTA-CORE-SOP-Risk Management.

5. References

HTA Code of Practice A: Guiding Principles and the Fundamental Principle of Consent

HTA Code of Practice E: Research; Code of Practice and Standards

6. Risk Assessment

A risk assessment for this HTA governance SOP is not required.

7. Definitions

A list of useful definitions of technical terms used within SU's HTA Core SOPs can be found in the HTA-Research Quality Manual.

8. Document History

Document History				
Version	**Review Date**	**Comment**	**Replaces**	**Reviewed by**
2.0	21/09/2015	Updated front page and footers. Updated links. Removal of appendix A to standalone template	1.0	Lisa Wakeman
3.0	01/09/2016	Post-licence grant review, amendment from acting designated individual reference; minor text amendments. Addition to definitions	2.0	Lisa Wakeman
4.0	18/04/2018	Amendments to reflect revised HTA Codes of Practice and Standards	3.0	Lisa Wakeman
5.0	07/02/2024	Revised SOP to reflect the separation of the previous joint HTA licence between SU and SUHB and to establish new SU procedures moving forward.	4.0	Bethan R Thomas & DI

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