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Human Samples in Research

Human Tissue Chain of Custody and Sample Labelling

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Document History

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2.0	21.09.15	Updated front page and footers. Updated links. Removal of appendix A to standalone template	1.0	Lisa Wakeman
3.0	01.09.16	Post-licence grant review, amendment from acting designated individual reference; minor text amendments. Addition to definitions	2.0	Lisa Wakeman
4.0	18.04.18	Amendments to reflect revised HTA Codes of Practice and Standards	3.0	Lisa Wakeman

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. This SOP applies to all Swansea University and ABM UHB staff and students who collect, use or store human tissue for the purpose of research in connection with disorders, or the functioning, of the human body.

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 HTA Governance Officer on request for submission to the HTA Annual Survey of Holdings. Failure to maintain accurate records may lead to the HTA revoking any licence issued to the organisation for the purpose of research and may have legal consequences for the University and Health Board.

2. Background

All human tissue samples should be traceable from the point of collection 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. This SOP and chain of custody log (*HTA-04-Template-Chain of Custody*) may be used alongside laboratory 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) carries the role of directing others in relation to the HT Act. As part of this role they have the ability to reasonably assist the DI in implementing procedures to ensure compliance with the HT Act and HTA licensing requirements.

It is the responsibility of the Principal Investigator (PI) or other relevant individual who is responsible for a tissue collection to implement a tissue tracking system wherever samples are transported or transferred between separate physical locations.

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

4. Procedure

1. 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.

2. Each tissue type, even if originating from the same donor/participant should be allocated a unique identifier e.g.

Donor/Participant ID: ABC001	
Whole blood sample	ABC001-1
Urine sample	ABC001-2
Saliva sample	ABC001-3
Tissue biopsy	ABC001-4

3. Multiple aliquots of a single sample should also be labeled with unique identifiers e.g.

Sample: ABC001-1	
Aliquot 1	ABC001-1A
Aliquot 2	ABC001-1B
Aliquot 3	ABC001-1C
Aliquot 4	ABC001-1D

4. 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 (see *HTA-04-TEMPLATE Chain of Custody*).

5. Chain of custody logs for all samples should be retained by the PI with the study/collection/biobankdocumentation and must be produced for internal and external inspections.

6. Guidance for transportation of human tissue can be found in *HTA-05-SOP-Transportation* and *HTA-06-SOP-Import and Export*.

7. All aspects of human tissue handling, including tissue traceability should be risk-assessed by the research team in line with *HTA-09-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

Acquisition - The collection and receipt of human samples. Consent from the donor must be in place unless exemptions to the consent provisions under the HT Act apply.

Audit - The evaluation of a system, process or procedure in order to ascertain its effectiveness and the validity and reliability of the information.

Chain of Custody - Documentation to evidence the chain of possession from sample collection until it reaches the laboratory or other final destination. It includes information such as sample number and location where sample was taken, dates and times of collection, type of sample and the name of person dispatching and receiving the sample. Every time the sample changes possession, the person relinquishing the sample and the person receiving it must sign and date/time the Chain-of-Custody form. For example, the sampler may relinquish the sample to a courier. At the transfer, both parties sign and date/time the form. Then the courier delivers the sample to the laboratory where now the courier and lab representative sign and date/time the form.

Designated Individual - The person who is authorised and, supervises the activities under a licence issued by the Human Tissue Authority (HTA).

Human Tissue – Any and all constituent parts of the human body formed by cells.

Human Tissue Act 2004 - Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The Human Tissue Act lists the purposes for which consent are required (Scheduled Purposes).

Human Tissue Authority - The independent regulator established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that collect, store and use human tissue for the Scheduled Purposes, for which appropriate consent is required (unless exemptions apply).

HTA Codes of Practice - Provide guidance and lay down expected standards for each of the sectors regulated by the HTA (e.g. research) and under the HT Act. They are designed to support professionals by giving advice and guidance based on real-life experience.

HTA Standards - Core standards in four key areas that must be met for an organisation to obtain an HTA licence, relating to the provisions in the HT Act and the regulatory requirements: Consent; Governance and Quality Systems; Premises, Facilities and Equipment; Disposal.

Person Designated: Individual appointed by the DI to assist them in supervising the licensable activities carried out within their organisation.

Principal Investigator – A Principal Investigator is the primary individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research.

Quality Management System - Centralised governance framework policies, procedures, training, provision of advice and guidance, documentation and data records relating to all aspects of acquisition, storage, use and disposal of human samples.

Relevant Material - Human samples that consist of or contain human cells. It excludes gametes and embryos, hair and nail from a living person; cell lines which have divided outside the human body and extracted DNA and RNA.

Research - A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications of new knowledge.

Risk Assessment - a careful examination of what could cause harm to people or resources. Workers and others have a right to be protected from harm caused by a failure to take reasonable control measures.

Scheduled Purposes - The activities relating to the removal, storage and use of human organs and other tissue that require consent, listed in Schedule 1 of the HT Act, e.g. research in connection with disorders or the functioning of the human body.

Standard Operating Procedure - Detailed, written instructions to achieve uniformity of the performance of a specific function which an integral part of a quality management system. In the context of research using human samples, SOPs document all the processes that affect the quality and safety of those samples (e.g. acquisition, storage, transfer and disposal).

Training Log (HTA) - A record of documentation regarding the training received and training support materials relating to the acquisition, storage, use and disposal of human samples in research, which is required to be constantly maintained and updated.