University of Leicester Research Governance Office Standard Operating Procedures relating to the Human Tissue Act 2004

SOP HTA-A1015 UoL

Management of Existing Tissue Holdings (obtained pre-2006)

Version 2.0

Effective Date: 01 December 2024

This SOP will be implemented in line with this document's effective date for all UoL HTA SOPs.

1.0 Introduction

This document has been produced in accordance with *The Human Tissue Act 2004* (HT Act). It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', and the Human Tissue Authority's *(HTA) Codes of Practice*.

Consent is the fundamental principle behind the Human Tissue Act (HT Act). The HT Act came into force on 1st September 2006 in England, Wales and Northern Ireland. After this date all HTA-relevant material must have a valid consent form stored with the samples to ensure compliance with the HT Act.

"Existing holdings" are samples collected pre-1st Sept 2006. These are HTA-relevant material, however under section 9 of the HT Act it is lawful to retain human tissue for research without consent if it was collected before 1st September 2006.

2.0 Scope

This standard operating procedure (SOP) is to outline the expectation regarding the management of samples that were collected before the HT Act came into force (i.e., samples collected pre-1st September 2006). It has been written in conjunction with the HTA Codes of Practice for research and the GaFREC SOP version 7.6 Sept 2022

Definitions:

CI	Chief Investigator
CTIMPs	Clinical Trials of Investigative Medicinal Products
DI	Designated Individual
HRA	Health Research Authority
HSC	Health and Social Care
HT Act	Human Tissue Act
HTA	Human Tissue Authority
NHS	National Health Service
PD	Person Designated
PI	Principal Investigator
REC	Research Ethics Committee
RGO	Research Governance Office
SOP	Standard Operating Procedure
UKECA	United Kingdom Ethics Committee Authority
UoL	University of Leicester

3.0 Procedure

As the consent requirements of the HTA Act are not retrospective, it is not a legal requirement to seek consent under the HT Act to store an 'existing holding' for a scheduled purposes. Although there is no statutory requirement for consent for the storage of an existing holding, it does not imply that all such material can be used freely and without regard to ethical considerations. If practical to do so, the consent of the participant should be sought and/or the views of the deceased person or of their relatives (if known) must be respected.

3.1 Transfer to UoL HTA Research Licence

"Existing holdings" must undergo the application process to be stored under the UoL HTA Research Licence as documented in HTA-A1001-UoL, to ensure there is appropriate oversight of the collection. The application should be facilitated by the custodian of the samples with the support from their PD to ensure the samples are officially registered on the UoL HTA Research Licence. Samples held under the UoL HTA Research Licence cannot be used.

Upon an application for the transfer of an "existing holding" to the UoL HTA Research Licence, the HTA Monitor, will arrange a date to view the "existing holding" in question and to ascertain how it was originally obtained. A consent audit will not be undertaken where there are no consent forms for those samples, but a consent template will be obtained where practical to do so.

3.2 Ethical review of research involving "Existing Holdings" of human tissue.

Ethical approval is required for the use of "existing holdings" and reference should be made to the guidance produced by the Health Research Authority (HRA). The HRA is the regulator responsible for ethical approval arrangements in health research.

Under the HT Act and the HTA Regulations, researchers in England, Wales and Northern Ireland will legally require NHS REC approval in order to carry out the following activities on "existing holdings":

- Storing or using HTA-relevant material from the living or deceased for a research project on premises without a licence from the HTA.
- Using the "existing holding" for research where the tissue is from a living individual and not identifiable to the researcher (the HTA licence is only for storage, not use).
- Analysing human DNA in material from the living (or using the results of the DNA analysis) without consent, in circumstances where they are unable to identify the donor and not likely able to do so in the future.

Although "existing holdings" are exempt for the consent provisions in the HT Act, the HTA licencing requirements still apply where the material is being held or used for research purposes.

3.3 Recognised REC definitions

Ethical approval which qualifies for exemptions under the HT Act can only be given by a recognised REC.

A recognised REC is an NHS REC (HSC in Northern Ireland) that is listed on the HRAs website, or a REC recognised by the United Kingdom Ethics Committee Authority (UKECA) that are competent to review Clinical Trials of Investigation Medicinal Products (CTIMPs).

A University Ethics Committee i.e., University Ethics and Integrity Committee (UEIC) is not considered to be a recognised REC for the purposes of the consent exemptions. Therefore, consent is required for tissue to be used in a research project approved by a University Ethics Committee, even if the research project uses tissue from the living, the researcher is not in possession, or likely to come into the possession of information that may identify the donor.

Recognised RECs can consider all applications relating to research involving the use of human tissue, even where this is conducted outside of the NHS.

3.4 Review and disposal of existing holdings

Collections of existing holdings are considered to be valuable for teaching or possible future research. However, the usefulness of these collections should be reviewed on a regular basis and, where items are found not to be of value, they should be disposed of sensitively and respectfully, and the details documented (SOP HTA-A1004-UoL).

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigator (CI/PI)	Chief Investigator / Principal Investigator (CI/PI) or delegate	Ensure existing holdings follow the procedure outlined in HTA-A1001-UoL. Ensuring the appropriate application for ethical approval for the use of the material is sought.
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Keeping SOP up to date to reflect any changes in the legislation / or regulations.
Persons Designated (PD)	Persons Designated (PD)	Ensuring existing holdings collections are incorporated onto their PD reports.
Designated Individual (DI)	Designated Individual (DI)	Ensure suitable practices take place within the licenced establishment.

5.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Amanda Sutcliffe	HTA Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding	28/11/2024 

6.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
November 2024	v2.0	A Sutcliffe	• Administrative updates • Removal of section research with identifiable data and consent exemptions. • Clarity around responsibilities • Update to title