UNIVERSITY OF LEICESTER

Paper copies of this document might not be the most up to date version.

The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

SOP: HTA-A1015-UoL

Version Number: 1.0

Effective Date: January 2021

Supersedes: N/A

Last Review Date: N/A Next Review Date: Jan 2023

Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
Author	Amanda Sutcliffe	HTA Monitoring Officer		08/02/2021
Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
Authoriser	Professor Peter Bradding	Designated Individual		08/02/2021

Background

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 material must have a valid consent form stored with the samples to ensure compliance with the HT Act.

"Existing holdings" (i.e. Samples pre 1st Sept 2006) are materials from the living or deceased that was already held for a scheduled purpose(s) when the HT Act came into force i.e. Relevant or bodily material held prior to 1st September 2006 for research.

Purpose and Scope

This standard operating procedure (SOP) is to outline the expectation regarding samples that were collected before the HTA act came into force (i.e. samples pre 1st September 2006). It has been written in conjunction with the HTA codes of practice for research and the RES SOP version 7.4 June 2019.

Definitions:

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	Persons Designated
REC	Research Ethics Committee
REGI	Research Governance Ethics and Integrity
SOP	Standard Operating Procedure
UKECA	United Kingdom Ethics Committee Authority
UoL	University of Leicester

Roles and Responsibilities

It is the responsibility of the Designated Individual (DI) to ensure that suitable practices take place within the licensed establishment that comply with the HT Act and the Human Tissue Authority (HTA) Codes of Practice.

It is the responsibility of the HTA Monitoring Officer to ensure this SOP remains fit for purpose taking into consideration any changes in legislation and changes to the HTA Codes of Practice for research, in addition to any changes in the HRA RES SOP.

It's the responsibility of the Persons Designate (PD) to assist the DI in implementing and adhering to the governance processes and ensuring relevant material held by researchers collected pre-2006 are logged on their local tissue registers once an application for the samples being transferred to the University of Leicester (UoL) HTA licence is approved.

Procedure to follow

As the consent requirements of the HTA Act are not retrospective, this means that legally it is not required to seek consent under the HT Act to store or use an 'existing holding' for a scheduled purposes.

"Existing holdings" must undergo the application process to be stored under the UoL HTA Research Licence as documented in SOP *HTA-A1001*, 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.

Upon an application for the collection of "existing holdings", the HTA Monitoring Officer, will arrange a date to come and view the "existing holdings" in question and to ascertain how they were originally obtained. A consent audit will not be undertaken where there are no consent forms for those samples. Although where possible a consent template will be obtained where practical to do so.

Although there is no statutory requirement for consent for the storage and use 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.

Requirements for ethical review of research involving "existing holdings" of human tissue

Ethical approval may be required for the use of the "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 ethical approval in order to carry out the following activities on “existing holdings”:

- Storing or using tissue of the living or deceased individuals for a research project on premises without a licence from the HTA.
- Using the “existing holding” for research (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.

Research with identifiable data

Consent is normally required to use identifiable patient information / data in research. In circumstances where researchers do not have consent to use identifiable patient data, they should refer to the HRA for further guidance. Obtaining consent may be preferable to developing complex systems for keeping samples unlinked.

Consent exemptions

Regardless of the date the material was donated for research, if it exceeds 100 years since the individuals’ death, consent to undertake research with the material is not required under the HT Act.

There is a further statutory consent exemption for the use and storage of human tissue for research if the following three conditions are all met:

1. The material was obtained from a living person;
2. The researcher is not in possession, or likely to come into possession of the information that identifies who the material came from;
3. Where the material is used for specific research project that has REC approval (NHS REC approval).

There may be occasions when a clinician involved in the research may also have access to a secure database that links the identification of the sample to the individual who donated the material. Providing the research material is not identifiable to the researcher (if it has a unique laboratory accession number) and the researcher does not seek to link the sample to the patient, it will still be regarded as

non-identifiable to the researcher and is permissible without consent if approved by a recognised REC. This does not mean that the samples must be permanently unlinked.

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 a 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) to review 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 exemption. 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.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions.

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)

Distribution Record:

Date	Name	Department	Received Y/N