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

SOP HTA-A1003 UoL

Storage of HTA-relevant materials beyond NHS REC approval

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*.
When applying for project-specific Health Research Authority (HRA)/Research Ethics Committee (REC) approval through the Integrated Research Application System (IRAS), the project-specific application form may not be used to seek open-ended approval for the use of stored tissue in future research programs. Nor is it permitted to submit substantial amendments to approved projects in order to use the tissue for another project with a different set of research questions.

Where a researcher makes a project specific application but then plans to store the material beyond the life of the project for use in future projects, there are a number of options available.

This SOP will outline the requirements for the long-term storage of HTA-relevant material pending use in future research projects as per IRAS option: "storage by research team pending ethical approval for use in another project".

2.0 Scope

This SOP has been produced in accordance with the Human Tissue Act 2004 and the Codes of Practice issued by the HTA, in accordance with the HRA regarding sample storage of relevant material. The SOP outlines the expectations of samples in long term storage once project specific REC approvals have expired.

Definitions:

AB	Adrian Building
CI	Chief Investigator
DI	Designated Individual
GGH	Glenfield General Hospital
LGH	Leicester General Hospital
HB	Hodgkin Building
HRA	Health Research Authority
HWB	Henry Wellcome Building
HTA	Human Tissue Authority
IRAS	Integrated Research Application System
LRI	Leicester Royal Infirmary
MHRA	Medicines and Healthcare products Regulatory Authority
PD	Person Designated
PI	Principal Investigator
REC	Research Ethics Committee
RGO	Research Governance Office
RKCSB	Robert Kilpatrick Clinical Sciences Building
RTB	Research Tissue Bank
SOP	Standard Operating Procedure
UoL	University of Leicester

3.0 Procedure

This SOP outlines the processes required to be followed at the end of the study where the CI/PI would like to retain the material beyond the scope of the original research project, where the material has the relevant consent for future research purposes. The remaining material will not be governed under the ethics of an NHS REC-approved Research Tissue Bank (RTB) until the study has undergone a formal HTA (internal audit) and has formerly transferred to the tissue bank as a collection of samples (specifically for RTBs that accept samples from project specific studies).

3.1 End of Study Processes

Upon completion of an NHS REC project-specific research study, at the end of the study you will have to notify the REC of the end of the study using the appropriate form(s) and providing any applicable final reports to the appropriate body(ies) i.e., REC/Medicines and Healthcare products Regulatory Authority (MHRA) within defined timelines (usually within 12 months of study completion).

Samples may be held after the declaration of the end of the trial, for analysis or verification of research data for up to one year as defined within the protocol. After this period legal authority to hold any human tissue under the ethical approval will expire.

If HTA-relevant samples (e.g., tissue) are to be held after the end-of-study for future use, the CI/ PI/ Researcher may make a further project-specific NHS REC application that must be submitted no later than the date on which the first project ends (as defined in the protocol). Please submit the new project using the Universities Research Management System that is used to register your research and obtain any reviews or approvals that your project requires. If this option is not in place, then where the original consents permit, tissue must be stored for future use under the remit of a HTA Research Licence. **This covers storage but not use.**

3.2 Research Licence 12384 Geographical location

Any relevant material that is to be stored beyond the original ethical approval from an NHS REC-approved study, must be relocated to a building that is covered by the UoL HTA Research Licence 12384 for storage, if not already stored within that area during the active study phase. All samples being transferred to the HTA Research Licence should follow the application process as documented in HTA-A1001-UoL.

The HTA Research licence covers the Glenfield General Hospital (GGH), Leicester General Hospital (LGH), the Robert Kilpatrick Clinical Sciences Building (RKCSB) located at the Leicester Royal Infirmary (LRI), UoL Main Campus buildings, which include the Henry Wellcome Building (HWB), Hodgkin Building (HB), Maurice Shock Medical Science Building (MSB) and the Adrian Building (AB).

It is important to be aware that any HTA-relevant material to be stored beyond the NHS-REC-specific research project requires an application for transfer to the UoL HTA licence detailed in HTA-A1001-UoL and in conjunction with HTA-A1008-UoL and HTA-A1009-UoL

Only samples from studies with the appropriate future research clause within the consent forms will get approval for transfer to the HTA research licence, unless further permissions have been sought from the original approving NHS REC committee.

In addition, if the end of study plans that were documented within the original Integrated Research Application System (IRAS) application form have changed, before officially notifying the study closure to the regulatory bodies, it is recommended to update the end-of-study plans by submitting a substantial amendment before closing the study to update the actual plans for the end of study samples.

3.3 Future Use of Samples

Once the samples are stored in an HTA-compliant area i.e., an area located within the licence footprint, the samples must not be used without further ethical approval being sought or before transferring them to an NHS REC-approved research tissue bank (RTB). The options are therefore;

1. Transfer the samples to an NHS REC-approved RTB
2. Hold them pending ethical approval in a new project-specific NHS REC application. They can be used once this in place

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigator (CI/PI)	Chief Investigator / Principal Investigator (CI/PI) or delegates	Ensuring samples obtained from NHS REC approved projects (sponsorship pathway projects) are located to HTA licenced on completion. Ensuring further approvals are sought for further use of the materials and new approvals are registered on the Universities Research Management System.
Research Governance Office (RGO)	HTA Monitor or equivalent in RGO.	Ensuring SOP is kept up to date, including changes in regulatory requirements and legislative updates.
Designated Individual (DI)	Designated Individual (DI)	Ensuring suitable practices are in place within the licenced establishment.
Person Designated (PD)	Person Designated (PD)	To assist the DI in implementing and adhering to the HTA governance processes.

4.0 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

5.0 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 changes • Addition of the Universities Research Management System • Clarity around future consent clause and end of study changes • Minor changes to future use of samples