UNIVERSITY OF LEICESTER

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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.

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## Development and Approval Record for this Document

| Role | Name | Job title | Signature | Date |
|---|---|---|---|---|
| Author | Amanda Sutcliffe | HTA Monitoring Officer |  | 17/02/2021 |
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## Background

There is a misconception that once human tissue samples are no longer under Research Ethics Committee (REC) approval they then fall under the remit of the UoL HTA research license and that this process happens automatically. However, this is not the case.

When a REC approval is due to expire, there are 2 options regarding the future storage and use of human tissue samples (and related HTA-relevant material).

Option 1: If the original primary and secondary analyses have not yet been completed, or have generated further related work, then a request to the REC for an extension of the study through an amendment is appropriate.

Option 2: If an extension to the REC approval is not needed, but there is consent for the storage and future use of the samples, they can be transferred to the HTA licence. This licence covers storage not use. Future use will then require either, i) further REC approval, or ii) transfer to a REC-approved Research Tissue Bank (RTB) though which tissue use is governed (see *HTA-A1002*) (Tissue in REC-approved RTBs still requires reporting under the HTA licence).

This SOP is to clarify the process that is required for the transfer of any remaining human tissue samples from a REC approved study to the HTA research licence when the ethics expires or has expired. To-reiterate, the licence only covers storage of the material, not use. Tissue can only be used following options 2 or 3 above.

An application for all tissue to be stored at the end of UHL- or UoL-sponsored studies must be received to the REGI Office and to the Designated Individual (DI) to ensure compliance with the HTA Research Licence 12384.

Those who are responsible for the notification of the end of study must notify the original REC that any remaining samples will be transferred to the UoL HTA Research Licence for storage. Remember, consent for future storage and use of the samples must be in place. Please see HTA-A1001 Appendix 1.

## Purpose and Scope

This SOP describes the process for samples to be reported at the end of the study 1) the form functions as an application form for relevant material to be transferred to, and reported against, the UoL HTA research licence 2) the reporting of Non-Relevant Material that is being retained beyond the scope of the original research project for auditing purposes.

This SOP applies to all UoL staff and students and any external visitors who conduct research on the UoL premises. It is particularly applicable to CI/PIs of UHL- and UoL-sponsored studies where samples are collected for research purposes.

Definitions:

CI Chief Investigator

DI Designated Individual

HRA Health Research Authority

HT Act Human Tissue Act

HTA Human Tissue Authority

MHRA Medicines and Healthcare products Regulatory Agency

MTA Material Transfer Agreement – A contract that governs the transfer of tangible research materials between two organisations, when the recipient intends to use it for his or own research purposes.

PD Persons Designated

PI Principle Investigator

PIS Participant Information Sheet

REC Research Ethics Committee

REGI Research Governance Ethics and Integrity

RTB Research Tissue Bank

SA Substantial Amendment

SOP Standard Operating Procedure

UHL University Hospitals of Leicester

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 HTA Codes of Practice. The DI must act as a gatekeeper for any material that is to be reported on the UoL HTA research licence.

It is the responsibility of the HTA Monitoring Officer to ensure that each sample collection reported on the HTA licence has undergone a full 100% consent audit before the samples can be given approval for transfer to the licence. In addition, the HTA Monitoring Officer is responsible for ensuring this SOP remains fit for purpose taking into consideration any changes in legislation and any changes to the HTA Codes of Practice for research.

It's the responsibility of the Persons Designate (PD) to assist the DI in implementing and adhering to the governance processes and to ensure researchers are aware of this process that requires to be undertaken for all sample sets that require reporting against the licence.

All researchers involved in the collection, storage and use of the material have the responsibility to ensure any samples that they retain custodian ship of, undergo this formalised process of transferring the samples to the research licence. Non-relevant samples must be documented, but will not be reported on the licence.

## Procedure to follow

This is the procedure to be followed to transfer any samples that are remaining from any REC-approved studies to the HTA research licence for the ongoing storage of the materials while they are not under REC approval. This process has replaced the end of study form for UoL sponsored studies.

### Defining the End of Study

The definition of the end of study must be specified in the study protocol e.g. last patient last visit or completion of final analysis. Any change to this definition is classified as a Substantial Amendment (SA) requiring notification to the NHS REC and to the MHRA where applicable.

At the end of the study, you are required to report the end of study to the Sponsor and any regulatory bodies involved with the study, simultaneously notifying the REC of the end of study using the form published on the *HRA website* and simultaneously or earlier, if the samples are not going to be destroyed, an application must be made

to the DI and the HTA Monitoring Officer for the transfer of the samples to the UoL HTA Research Licence. It is illegal to store HTA-Relevant Material outside a REC-approved study or an HTA licence.

## Tissue Samples

If tissue samples have been acquired as part of the research study then the investigator must comply with the conditions of the favourable ethical opinion and the informed consent document signed by the participants.

Where the intention is to store the samples, pending a favourable ethical opinion for use in another research project (as detailed in the NHS REC form) then this must be in place within 7 days before the of the end of study. Otherwise, the tissue samples must be either moved to a RTB licensed by the HTA, held in a HTA licenced area and reported on a HTA licence, or destroyed. Failure to do this is a breach of the favourable ethical opinion and of the Human Tissue Act (HT Act).

## Tissue Samples from participating study centres being transferred to UoL

If materials are to be transferred to UoL from other participating study centres where UoL is the Sponsor, there must be a contract in place to govern the transfer of the samples. If the study is a Clinical Trial of Investigational Medicinal Products (CTIMP), this may be embedded within a model Non-Commercial Agreement (mNCA). Non-CTIMP studies, will require a separate MTA to govern transfer of the materials, and where possible (depending on the conditions of the REC favourable opinion / consent provisions) the original consent form must be shared with the custodian of the samples to ensure compliance with the HTA.

## Application to the DI

After initial notification to the REC for the end of study, please refer to end of study reporting requirements for research studies. Investigators must apply for their remaining samples to be stored under the UoL research license 12384 using the application form (HTA-A1001 Appendix 2).

The initial application will be reviewed by the HTA Monitoring Officer who will then contact the study team to organise a date for a 100% consent audit to be undertaken in addition to a sample audit.

## Consent Audit

The HTA Monitoring Officer will undertake a 100% consent audit to ensure the consent provision for future use is in place for the storage of the material after the REC approval has expired. Any samples that are to be retained must have a valid consent form (i.e. completed correctly) and the original consent form must be retained on site at all times during the samples life. This can either be as a hard copy of an electronic copy, or both.

Access to all the study documents, consent forms, samples logs and storage areas will be required to facilitate the audit.

## Valid Consent

A valid consent form, is a consent form that has had the boxes initialled by the participant, this must include the box relating to future use if present on the consent form.

In the absence of the future use clause the samples would not be able to be transferred to the HTA licence as there is not the correct consent provision in place to facilitate the storage beyond the scope of the original research project. A copy of the original patient information sheet (PIS), forms part of the informed consent process, therefore important that a PIS is also available to review.

The participant must have printed their name, signed and dated in the areas provided for them, and the name of the person taking consent should also be printed with their signature the date the consent was taken.

However, again for older studies, it may state in the PIS that personal details will not be shared outside the research study team, which may be particularly relevant for tissue received from other centres. In this case, we need as a minimum, a blank consent form and a PIS, and an MTA from the supplying centre stating that a full consent audit has been undertaken before the samples are sent.

## Storage of Consent forms

A number of methods can be used to store the consent forms. They can either be stored as a hard copy in either a fire retardant cabinet/storage boxes with lids in a secure area or as an electronic copy on the R:Drive at UoL, or both. Either way these must be readily accessible at all times for audit purposes.

## DI Approval

Once an audit has been undertaken, the DI and the HTA Monitoring Officer will convene to discuss the application in detail. For samples to be transferred to the Research Licence, valid consent must exist, the terms of the storage of the consent forms have to be agreed, and the storage facilities must adhere to the HTA Codes of Practice.

## Approval Offer

Providing the samples can be maintained within the HTA Codes of Practice, the sample transfer request will be approved, and email confirmation will be send from the DI. In some circumstances, some of the sample may have to be disposed, particularly, if there is no future consent clause.

Providing the correct consent provision is in place, and that the samples can be stored in a HTA licenced area, with temperature monitored facilities, the application will be approved by the HTA Monitoring officer and the DI. The HTA Monitoring Officer will give further advice on the audit report for to ensure the samples will remain compliant.

For any application for samples to be transferred to the licence, if these conditions cannot be met, then the application maybe declined, unless a suitable alternative can be found e.g. if a freezer is not on a monitoring system, but could be added to a monitoring system, a new probe could be obtained for that freezer to ensure it can then be stored as per the HTA standards.

## Conditional Offer

If an application to transfer samples to the license does not quite meet the HTA standards, but is easily rectifiable, the applicant maybe given a conditional offer. For example, if it is identified by audit that the storage facilities do not have a monitoring system already installed, the CI may have the opportunity to correct the findings from the audit by installing a monitoring system for the storage facilities, and thus making the storage facilities compliant.

## Declined Application

A declined application will only be issued if there is no alternative, i.e. if there are no consent provisions in place for future use, or this does not comply with the conditions

of the REC favourable opinion. This would be discussed with the applicant as there may be an alternative solution that could rectify this issue.

## Notification to the REC

Before submitting your End of Study notification to the REC, it is advisable to check Part B Section 4 and Section 5 of the IRAS form to ensure the information is correct. If the end of study arrangements have changed from what was documented in the original IRAS application form, it may be advisable to submit a SA to clarify the change in end of study arrangements before notifying REC of the study closure.

Once the end of study notification has submitted, you are unable to submit further amendments to the study. It is therefore important that this is checked before submitting your end of study notification to the REC.

If they are being retained for future use, providing the correct consent provision for this exists, within that report you should notify the REC that the remaining samples will be transferred to the Research Licence 12384 for the storage, or if applicable transferred to the governance of a REC-approved RTB.

## Non-valid consent or samples with no future use consent provision.

Samples that are from studies where the consent for future was not obtained, and where the consent forms have been identified as not valid by audit, must be disposed of and cannot be held under the Research License. The PD of the research area will be advised of the outcome of the audit and instructed that the material will require disposal.

The material will be stored in a suitable departmental holding area until the University of Leicester's Facilities Management can arrange disposal collection. Refer to University Estates and Facilities Management service level agreement and the disposal of samples SOP (*HTA-A1004).*

When the disposal is completed, any sample logs that researchers hold must be updated to log the date, reason and the method of disposal used to ensure compliance with the HTA codes of practice. Disposal logs are required to be retained for 5 years after the disposal has taken place.

## Approved Samples

Once the consent forms have undergone a full consent audit and the samples that are retained are checked for accuracy against the sample logs to ensure only samples with a valid consent form are retained. The HTA governance officer will ensure the application form is fully signed off with oversight from the DI.

A completed copy of the application form with be send back to the CI / PI in addition to the departmental PD for the departmental PDs to update the tissue register to ensure tissue registers are up to date and accurate.

## Non compliance

In the event of a non-compliance refer to *SOP (HTA-A1024).*

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) |
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