SOP Ref:	UOS_HT_SOP_14
SOP Title:	Continued storage of human tissue samples after the end of a study.
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Approval History				
Version 1.0	Name	Role	Signature	Date
Written By:	Andy McClave	Clinical Research Governance Officer		10.03.2020
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Version 2.0	Name	Role	Signature	Date
Revised by:	Linda McLatchie	Hub PD		02.06.2023
RIGO approval:	Gill Fairburn	Interim Director R&I Services		26.06.2023
DI approval:	Paul Townsend	DI		19.06.2023

1. INTRODUCTION

All human tissue samples which are collected and stored either under the University of Surrey Human Tissue Authority (HTA) Licence or which have a favourable opinion from a recognised NHS research ethics committee (NHS REC), as defined by the UK policy framework for health and social care research 2017, or other approved research ethics committee, can only be considered for continued storage under the HTA licence where explicit consent is given by the donor of the sample for use in future research.

2. SCOPE

This SOP applies to any University of Surrey researcher wishing to continue to store samples under the HTA licence from projects where the University of Surrey ethics committee (UEC) originally reviewed and gave a favourable ethical opinion. As well as any University of Surrey researcher who wishes to transfer samples from completed NHS REC studies to storage under the University of Surrey HTA licence. Only NHS REC studies where there is consent for the samples to be kept and/or used for future studies and where the samples have been fully logged and tracked such that sample integrity can be demonstrated, will be eligible.

3. RESPONSIBILITIES

3.1 The Designated Individual (DI) has *a legal duty to ensure that statutory and regulatory requirements are met. They are responsible for supervising licensed activities and ensuring suitable practices are taking place.* They should ensure that only samples with appropriate consent are continued to be stored or transferred to storage under the HTA licence at the end of a study and that researchers meet the HTA guidance for traceability for all samples.

3.2. The Persons Designated (PD) *assist the DI in ensuring compliance with HTA standards.* There is a PD for each of the areas; Stag Hill (Hub PD & FEPS PD), Leggett, VSM, VSP and Surrey CRB. The PDs are responsible for allocating storage space, monitoring and arranging transfer of samples where required and for keeping the Designated Individual (DI) informed of any concerns and problems regarding continued storage of samples.

3.3. The University's Human Tissue Research Operations Group (HTROG) are the governing body overseeing all human tissue work.

3.4. Principal Investigator (PI) is responsible for ensuring that they have the correct informed consent from all the participants to retain their samples beyond the approval period or end of study. That, all team members who handle human tissue samples have completed the required training and that all samples to be kept at the end of a study have been labelled and tracked to the required standard for ensuring full traceability. The PI must also apply for all necessary ethical approvals for any future research that is to be undertaken using the samples transferred to storage under the university licence.

3.5 The Research Integrity and Governance Office (RIGO) is responsible for monitoring and providing training for individuals who collect, store, or use human tissue for research. They are also responsible for keeping a central record of all studies, including those which are transferred to being held under the HTA licence at the end of REC approval.

4. PROCESS

4.1 Requirements that must be met for samples to be kept:

4.1.1. Consent. The most important consideration of whether samples may be retained at the end of a study is whether there is appropriate consent to do this.

- The consent form that the participants signed, must specifically ask for permission for the samples to be retained for future use at the end of the study
- Only samples where the participant has given this consent (i.e., that box has been signed or initialled) are eligible to be kept for future studies
- If there are any restrictions on what type of future study can be carried out any proposed future studies must satisfy these.
- Any restrictions on the transfer of the samples or any exclusions that individual participants have placed on future use must be checked and honoured.

4.1.2. Sample tracking and labelling. All samples to be kept must have been labelled, stored and tracked as detailed in SOP UOS_HT_SOP_10, human tissue sample labelling, storage and tracking, such that all the information below can be provided.

- Project title
- Principal Investigator details
- NHS REC ID (if relevant)
- Copy of FEO letter
- Dates samples were collected
- Details and documentation of any transportation
- Copy of blank consent form
- Location of consent forms and confirmation of consent status of participants
- Staff involved in sample collection
- Material type
- Number of samples being retained, down to the aliquot level
- Full sample logs for all samples to be retained, down to the aliquot level

- Volume of samples
- Who has responsible for the samples
- Storage temperature requirements for the samples

- Any compromises to storage temperature during previous storage/transport
- How long will samples will need be stored
- Will samples be stored pseudonymously, if so, who has access to the code
- Will samples be shared

4.1.3. **Sample viability**. All researchers wishing to retain samples for future studies must be able to provide evidence that the samples are still viable for the intended purpose, particularly if they have already been stored for a significant period.

4.1.4. **Purpose**. All samples to be kept must be being kept for a specific reason, as evidenced by an application for ethical approval to use them or justification for continued storage.

4.2. On completion of a Research Ethics Committee approved project:

- In cases where the samples meet the requirements in 4.1 above and the PI would like to retain the samples after the end of the study, they should complete and submit to: rigo@surrey.ac.uk, UOS_RIGO_template_014 'Transfer of Human Samples from NHS REC approved study to HTA Licence' application form, together with all approved participant information sheets and blank consent forms that were used during the lifetime of the study. This form should be sent as soon as possible but no later than 9-months after the end of the study to give time for a decision to be reached by the 12-month deadline set by the HRA for samples to be kept at the end of a study without need to transfer them to storage under a HTA licence or to renew the ethics.

- When approval is given for the transfer of samples to be held under the HTA licence then the transfer form will be returned signed by RIGO as evidence of approval. It is the PIs responsibility to keep a copy of this with their other documentation in their secure study master file. RIGO will also notify the PDs, who will then contact the PI to discuss any required changes in the storage location for the samples themselves and the sample tracking records.

- As ethical approval must be in place before the samples can be used, they will be placed in quarantine at the end of the REC approved study, until the PI has provided confirmation of ethical approval to the PD and RIGO.

- Whether the samples are to be retained or not, the PI must inform RIGO when their REC approved study has ended and copy RIGO into the end of study notification being sent to the Health Research Authority (HRA), as detailed on the HRA website.

- If the samples are either not eligible or not wanted to be retained for future research, they should all be destroyed in accordance with UOS_HT_SOP_13 Disposal of Human Tissue Samples, no later than 12 months from the end of the study date and this documented in the study file (UOS_HT_SOP_09, Records management). Consent forms should be kept for a minimum of 6 years from the end of the study.

4.3. On completion of a project with samples held under the HTA licence

- The principal investigator (PI) must inform RIGO and the site PD before the completion of their study whether, subject to their meeting the requirements in 4.1, the samples will be destroyed, sent somewhere else or retained for future use at the end of the study period.

- As ethical approval must be in place before the samples can be used for future studies, they will be placed in quarantine at the end of the study until the PI has provided confirmation of further ethical approval to the PD and RIGO.

- If the samples are either not eligible or not wanted to be retained for future research, they should all be destroyed in accordance with UOS_HT_SOP_13 Disposal of Human Tissue Samples and document in the trial master file, within a month of the end of the study. Consent forms should be kept for a minimum of 6 years from the end of the study.

5. ASSOCIATED DOCUMENTS

UOS_HT_SOP_03 Training requirements for using human tissue
UOS_HT_SOP_09 Human tissue records management
UOS_HT_SOP_10 Human tissue sample labelling, storage and tracking
UOS_HT_SOP_13 Disposal of human tissue samples

6. REFERENCES

HTA Code of Practice and Standards: Code E, Research

7. TRAINING

Before commencing any work with human tissue samples anyone wishing to do so must have completed all the training detailed in UOS_HT_SOP_03, Training requirements for using human tissue.

8. USEFUL ABREVIATIONS

HTA – Human tissue authority
HRA – Human Research Authority
HT act – Human Tissue act
LH - Licence holder
DI- Designated individual
RIGO – Research Integrity and Governance Office
HTROG – Human Tissue Research Operations Group
PD- Person Designate
SOP-Standard Operating procedure
AE/I - Adverse event or incident
GCP – Good Clinical practice
MTA – Material Transfer Agreement
REC – Research Ethics Committee
UEC – University ethics committee

9. REVISION HISTORY

Version number	Revision details	Author	Date
1.0	New documents (UOS_HTA_SOP_017 & 018)	Any McClave	10.03.2020
2.0	Major revision including new numbering and joining of two SOPS (UOS_HT_SOP_14)	Linda McLatchie	02.06.2023