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SOP Title:	Disposal of Human Tissue Samples
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Approval History				
Version 1.0	Name	Role	Signature	Date
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Approved By:	Ferdousi Chowdhury	Head of RIGO		10.02.2020
Version 2.0	Name	Role	Signature	Date
Revised by:	Linda McLatchie	Hub PD (acting)		02.06.2023
RIGO approval:	Gill Fairbairn	Interim Director R&I Services		26.06.2023
DI approval:	Paul Townsend	DI		19.06.2023

1. INTRODUCTION

Human biological samples are potentially hazardous substances and must therefore be handled and disposed of in accordance with the relevant University Health and Safety policies and procedures and the Department of Health's guidance Health Technical Memorandum 07-01: Safety management of healthcare waste. The management of human samples must also be in accordance with the donor's wishes and any relevant legislation, and this includes disposing of samples when required and maintaining disposal records.
The University of Surrey (the University) adheres to the requirements of the Human Tissue Act (HT Act) for handling relevant materials. The Human Tissue Authority's (HTA) Code of Practice for Research sets out the Traceability Standards that must be followed. This includes ensuring that there is full traceability from the point of sample collection to final disposal/disposition and that human tissue samples are disposed of in an appropriate manner.
The procedures set out in this SOP are based on the HTA Codes of Practice and applies to all human tissue research taking place at the University, covering the process for disposal of human tissue as required by the Human Tissue Act 2004 (HT Act).

2. SCOPE

This SOP applies to all projects, including those with Research Ethics committee approval using any type of primary human material including material that is considered relevant by the HT Act, any non-relevant human material, human DNA, RNA, and any human biological fluids.
All individuals, whether staff, student or visitor, conducting research with human material under the auspices of the University of Surrey must comply with this SOP which applies to the disposal of human tissue material as well as materials that have been in contact with relevant materials including those used to isolate, collect, manipulate and otherwise handle samples.

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*. This includes ensuring that all human tissue samples are fully tracked and disposed of appropriately.

3.2. The Persons designate (PD) *assist the DI in ensuring compliance with HTA standards.* There is a PD for each of the areas; Stag Hill (Hub PD and FEPS PD), Leggett, VSM, VSP and Surrey CRB. They are responsible for assisting researchers in following the guidance in this SOP and for monitoring human sample disposal. They are also responsible for reporting any problems or breaches concerning sample disposal to the DI.

3.3. The Human Tissue Research Operations Group (HTROG) is the governing body overseeing the storage and documentation of human tissue held under the HTA licence, which includes sample disposal.

3.4. The principal (or lead) investigator (PI) is responsible for ensuring that their study is fully documented and that all samples are fully labelling such that there is full sample traceability. This includes ensuring that all human samples regardless of whether they are stored under the authority of the HTA licence or have research ethics committee approval are disposed of in a safe and appropriate way that maintains the dignity of the samples and is in accord with the donor's wishes.

3.5. Laboratory technical staff are responsible for ensuring segregation of all laboratory waste streams including ensuring that all human tissue waste is disposed of appropriately and in a sensitive manor and that a certificate of destruction is requested when required.

3.6. All individuals, whether staff, student or visitor, conducting/supporting research activities with human material under the auspices of the University of Surrey must ensure that they adhere to this SOP with regards to disposal of human samples. This includes ensuring samples are disposed of when necessary and in an appropriate manner and that records are updated immediately following disposal. It is the responsibility of all individuals to report any problems or concerns in relation to disposal of their samples to the PD.

4. PROCESS

4.1 Reasons for disposal. Human tissue samples may need to be disposed of for a number of reasons as listed below. In all cases the reason for disposal should be recorded:

- When a participant withdraws consent for storage of their samples
- If there is doubt about whether the required consent is in place and the samples are not under the responsibility of another institution
- When samples have been damaged such as a freezer failure or transport problem
- When sample quality or validity is in question, due to use of incorrect or no approved protocols
- When a sample isn't labelled, clearly enough to identify it
- When there is too little sample left for further analysis
- If there is surplus tissue
- When research is complete and the sample is no longer needed for the purpose for which it was collected and there is either no consent to keep if for future work, or the researcher does not have any research need to keep it for a future project.
- If disposal is required to comply with the terms of a MTA or other legal agreement at the end of a study
- When samples are not compliant and corrective action is not possible within a feasible time frame

4.2. General guidance. Human tissue samples should always be treated with dignity and respect, and this includes the process of disposal, and should not therefore be disposed of with animal tissue or general clinical waste. The University of Surrey is not able to dispose of human tissue by cremation or burial and so this should be considered when the decision is made whether to accept samples from particular sources or not. This is particularly important when samples are being considered for import for example from a place where local customs or expectations may be different. The consent given by the donor and methods described in the MTA or equivalent legal agreement for disposal must be checked before samples are shipped and/or accepted. Samples that require cremation or burial should not be accepted unless they can be returned for disposal.

4.3. Types of bins to use and tagging procedure.

4.3.1. Yellow burn-bins or sharps bins should be used to dispose of human samples by incineration, examples of these are shown in Figure 1 below.

4.3.2. Relevant human material MUST NOT be disposed of with any animal tissue or general clinical waste, unless in contact with animal tissue is part of the approved study protocol. Each clinical waste bin should only contain human tissue and any containers or paper etc. that have come into contact with human tissue.

Figure 1- Yellow sharps and burn Bins suitable for disposal of human tissue by incineration

4.3.3. Burn bins should be double lined with yellow clinical wase bags and contain sufficient absorbent material (e.g., Vermiculite) to absorb any liquid that could spill if all the samples were to leak.

4.3.4. Disposal of human tissue should involve two people so that samples can be checked by both individuals and the second person can act to witness that the samples listed have actually been disposed of. This is particularly important where samples are being disposed of because a participant has withdrawn consent for their samples to be stored.

4.3.5. All bins should only be filled to the fill line which is approximately ¾ full.

4.3.6. The yellow clinical waste bags should be securely sealed with a cable tie within the burn bin before the lid is closed.

4.3.7. Once securely closed, all these containers should have a blue waste tag added and the number of this recorded.

4.3.8. To obtain a certificate of destruction, which is required for all samples that have been stored, a red tag bearing the words, 'HTA waste', should be added (see Figure 2) and the bin photographed. A copy of the photo together with the completed request for a certificate of destruction form (appendix 1) should then be sent to the clinical waste manager who will request a certificate of destruction from the company disposing of the waste. The name of the clinical waste manager and copies of the red tags can be obtained from the local lab manager or PD or by emailing HTAlabfacilities@surrey.ac.uk.

Figure 2: Yellow burn bin with blue waste tag and red HTA waste label required to request a certificate of destruction.

4.3.9. Once sealed and labelled the bin can be stored in a walk-in cold room or -20°C freezer on a short-term basis before disposal if necessary.

4.3.10. When placed in the clinical waste collection area this should be a secure location. Sharps bins can be either similarly tagged and taken to the nearest approved disposal area or collected in accordance with the local safety regulations (FHMS MAN-22 and SOP-183)

4.4. Additional guidance for specific types of samples:

4.4.1. Samples with a biohazard risk. Relevant material, which has a high biohazard risk (for example, known to contain Hazard Group 3 pathogens), should be processed in accordance with University safety rules (FHMS MAN-22 and SOP-183) to minimise risk before being placed in the designated yellow clinical waste bags within the burn bin. If you are unsure if your samples have a high biohazard risk, further advice should be sought from the University's Biological Safety Officer or the PD.

4.4.2. Radioactivity risks. Disposal of relevant material that has been subjected to any radiolabelling procedure must be discussed with the University's Biological Safety Officer and Radiation Protection Officer to identify safe routes of disposal.

4.4.3. Surplus tissue, such as trimmings from the microtome tray should be disposed of as clinical waste. Trimmings that are floating should be picked up with a pair of forceps and wiped with a small piece of tissue. Any human tissue that becomes attached to equipment during tissue processing such as in a cryostat should be similarly removed. These processes need to be logged and the waste tag number recorded but do not need a certificate of destruction. If only small amounts are generated at a time, these may be kept in a fully and clearly labelled bag or container under the same conditions as the samples themselves and disposed of in batches, at sensible time intervals.

4.4.4. Fresh and unfixed relevant material should be put inside sealed primary containers such as blood tubes or sample collection pots before adding to the burn bin.

4.4.5 Urine. Small aliquots of urine (up to 50ml/tube) may be disposed of as described above with sufficient absorbent material in case the tubes leak. Larger quantities should be treated with disinfectant (at appropriate concentration for appropriate time) before being disposed of via one of the following routes:

- A laboratory sink, with plenty of running water.
- A sluice with plenty of running water.
- A flushable toilet.

In these cases, the method, time and date of disposal should all be logged and witnessed by a second researcher as in 4.3.4. above when the urine has been stored.

4.4.6. Acellular body Fluids. Any acellular components of bodily fluids can be discarded in accordance with University safety rules (MAN-22 and FHMS_SOP-183).

4.4.7. Other body fluids. Unwanted blood fractions and the contents of open tubes can be treated with disinfectant (at appropriate concentration and contact time) before either being discarded down a laboratory sink with plenty of running water or placed into designated yellow clinical waste bags with plenty of absorbent material. Cellular components in closed tubes can be placed directly into the bag within the burn-bin.

4.4.8. Tissue sections or cytology specimens on glass slides. All relevant material including whole or part cells mounted onto glass slides should be discarded in a yellow sharps bin, which should be tagged and treated in the same way as the yellow burn bin to obtain a certificate of destruction.

4.4.9. Pregnancy loss remains – If working on any samples that come from pregnancy loss it must be checked before obtaining these samples that there is permission for incineration. Where this is the case, these samples should be disposed of in a separate container to give them due respect.

4.4.10. Commercially purchased samples that haven't been stored. Where human blood or other samples are purchased and then processed without storage, they should still be disposed of via tagged yellow burn bins following the guidance above for including sufficient absorbent material. Waste tag numbers should be recorded, and clear records kept of the processing steps.

4.4.11. Items contaminated with human tissue. Any items that are sharp-edged, glass or sharps that have come into contact with human tissue and could therefore have human cells on them should be handled in accordance with FHMS-SOP-97 and disposed of in a sharps bin as shown in figure 1. Similarly, any empty containers that have come into contact with human samples and could therefore contain residual cells, must be treated as containing relevant material and placed into a designated yellow clinical waste bags or burn bins.

4.4.12. Disposable equipment that has been in contact with relevant materials including scalpels, microtome blades, phlebotomy disposables, disposable gloves, processed in accordance with University's safety rules (FHMS-MAN-22) to minimise the infection hazard before being placed in designated yellow clinical waste bags or sharps bins as appropriate.

4.5. Summary of routes for disposal of human samples

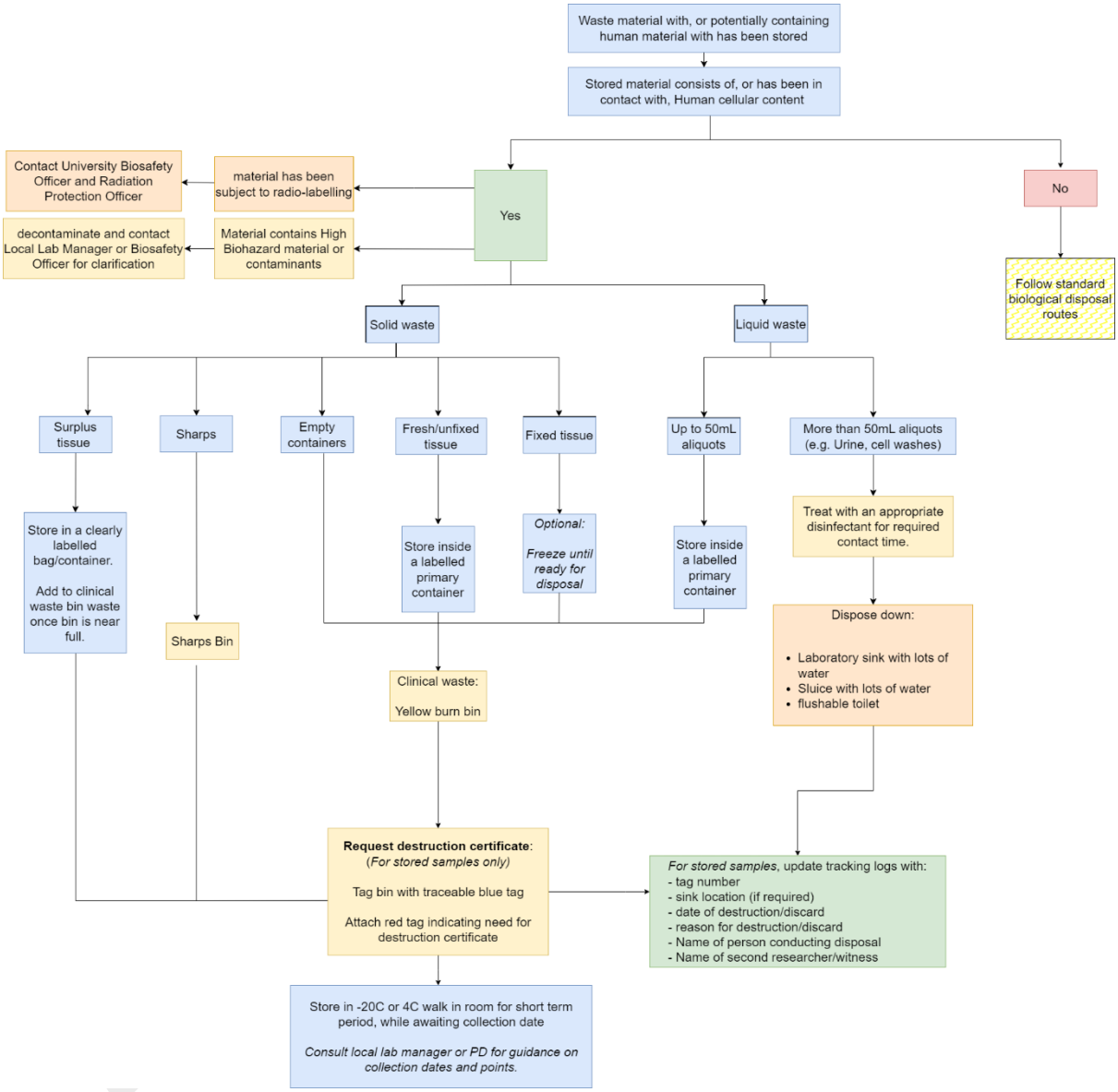

Figure 3: Summary diagram showing the main routes of disposal of human samples

4.6. Disposal Records and Documentation. All disposal of stored human tissue samples must be fully documented by the PI. This includes keeping the certificate of destruction once issued with the other study documentation for at least 5 years.
The sample records on eLab Inventory (or alternative approved system) should be updated immediately after disposal by completing the disposal section for each sample with:

- The date of disposal (added to box)
- Reason for disposal (selected from pull down menu)
- Method of disposal if not by incineration
- Waste tag number added and location of destruction certificate
- Indication of volume disposed of if not the whole sample

Once this information has been added for each sample, the sample record can then be 'deleted' from the system. This moves it from the storage location to the archive, under the name of the person who was listed as the sample owner at the time of deleting. Where a PI has granted temporary ownership of samples to another member of the group it should be clarified who will be responsible for 'deleting' samples as ownership cannot at that point be reverted to the PI and it is preferable to have the full list of disposed of samples under the same owner to allow easy export of the list if required.

5. ASSOCIATED DOCUMENTS

On FHMS Q-Pulse Document Management System and University Health and Safety SharePoint site

- Biosafety Manual FHMS MAN-22
- Disposal of Biological Waste FHMS SOP-183
- Safe use and handling of sharps SOP-97

UOS_HT_SOP_03 Training requirements for using human tissue

6. REFERENCES

- Health Technical Memorandum 07-01 – Safe management of healthcare waste, Department of Health
- 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 ABBREVIATIONS

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 document (UOS_HTA_SOP_016)	Chris Bradley	05.02.2020
2.0	Major revision including new number (UOS_HT_SOP_13)	Linda McLatchie	02.06.2023

Appendix 1 – Copy of form for requesting a certificate of destruction – template available from HTAlabfacilities@surrey.ac.uk.

University of Surrey - Health & Safety Department

Certification of Destruction Request Form

Date of Collection:	
Customer Name:	**UNIVERSITY OF SURREY**
Customer Address:	
Material to be destroyed:	
Study Name:	
Tag Number:	
Container Type:	

*** N.B - To be completed by the Health & Safety Department / Grundon***

Waste Transfer Note number:	
Consignment note number:	