RESEARCH & INNOVATION SERVICES
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RESEARCH INTEGRITY AND GOVERNANCE OFFICE

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SOP Title:	Disposal of Human Tissue Samples
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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.

2. SCOPE

2.1 This SOP applies to all projects (including NHS REC approved studies) 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.

2.2 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.

2.3 All researchers working with human material must ensure their study has been registered centrally with the Research Integrity and Governance Office (RIGO) through making an application for the use of human tissue. Research with human tissue cannot take place without the appropriate ethics approvals being in place.

2.4 This SOP also applies to the disposal of materials that have been in contact with relevant materials including those used to isolate, collect, manipulate and otherwise handle samples.

3. RESPONSIBILITIES

3.1 All individuals working with human material must ensure that they adhere to this SOP with regards to disposal of human samples. This includes ensuring samples are disposed of 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 Person Designated (PD) and RIGO.

3.2 The Principal Investigator (PI) is responsible for that only appropriately trained individuals are allowed to handle human samples for their studies.

3.3 All individuals collecting, storing or using human tissue for research under the University's HTA research licence are accountable to the relevant PD(s) and the Designated Individual (DI).

3.4 The Persons Designated (PD) are responsible for supporting the training of individuals on this SOP. They are also responsible for monitoring human sample disposal at the sites registered under the University's Human Tissue licence (under direction from the University's Human Tissue Research Operations Group (HTROG)).

3.5 Laboratory technical staff are responsible for ensuring segregation of all laboratory waste streams including any generated HTA-relevant material for collection by the university approved licenced contractor.

3.6 The University's Biological Safety Officer is responsible for ensuring the processes described in this SOP adhere to any statutory and best practice Health and Safety standards.

4. PROCESS

4.1 Fresh/unfixed cells or tissue

4.1.1 Fresh or unfixed relevant material must be held in sealed primary containers (e.g. blood tubes, sample collection pots) before placing into designated yellow clinical waste bags or burn bins. Larger solid specimens may be placed into a burn bin with at least 5cm depth of absorbent material (e.g. Vermiculite) in the bottom of the burn bin and lined with two yellow clinical waste bags.

4.1.2 Empty specimen containers that have been in contact with the specimen and, therefore have residual cells, must be treated as containing relevant material and placed into a designated yellow clinical waste bags or burn bins.

4.1.3 Any burn bin or sharps bin used for disposal of relevant material must be labelled "**Waste Human Material for incineration**."

4.1.4 Any human material, which becomes attached to equipment during tissue processing (e.g. cryostat chamber) should be removed with forceps or a small amount of medi-wipe tissue and discarded in the designated yellow clinical waste bag. The equipment must be disinfected after use.

4.1.5 Animal tissue and other clinical waste MUST NOT be disposed of in the same designated human material clinical waste bag, sharps bin or burn bin.

4.1.6 The designated yellow clinical waste bags and burn bins must be securely sealed and tagged and taken to clinical waste bins in local disposal areas.

4.1.7 Relevant material, which has a high biohazard risk (e.g. known to contain Hazard Group 3 pathogens), should be processed in accordance with University safety rules (MAN-22 and Health and Safety SOP-183) to minimise risk before being placed in the designated yellow clinical waste bag for incineration. 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.

4.1.8 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.

4.1.9 If it is not practical to immediately dispose of material, then it may either be placed in a designated yellow clinical waste bag or burn bin and frozen in a designated freezer or cold storage at -20 °C or lower for short term storage.

4.2 Body Fluids

4.2.1 All acellular components of bodily fluids (e.g. plasma, filtered urine) can be discarded in accordance with University safety rules (MAN-22 and Health and Safety SOP-183).

4.2.2 Cellular components, unwanted blood fractions and the contents of open tubes can be neutralised with disinfectant (at appropriate concentration and contact time) before either being discarded down a designated laboratory sink with plenty of running water or placed into designated yellow clinical waste bags containing absorbent granules and labelled 'Waste Human Tissue for Incineration'. Cellular components in closed tubes can be placed directly into a burn bin labelled "Waste Human Material for incineration."

4.2.3 Specimen containers that have been in contact with the specimen and, therefore have residual cells, should also be disinfected and discarded in the designated yellow clinical waste bag. Any glass or sharp-edged containers should be placed in a yellow sharps bin to avoid risk of injury or spillage.

4.2.4 Animal tissue and other clinical waste MUST NOT be disposed of in the same designated human material clinical waste bag, sharps bin or burn bin.

4.2.5 Bags, sharps bin and burn bins should be tagged and taken to clinical waste bins in local disposal areas.

4.2.6 Sharps bins should be tagged and either taken to local disposal areas or collected in accordance with local safety regulations

4.2.7 Relevant material, which has a high biohazard risk (e.g. known to contain Hazard Group 3 pathogens), must be processed in accordance with University safety rules (MAN-22 and Health and Safety SOP-183) to minimise risk before being placed in the designated yellow clinical waste bag or sharps bin for incineration.

4.3 Fixed, paraffin-wax embedded tissue

4.3.1 Trimmings from the microtome tray or those that have adhered to the microtome should be placed into a designated yellow clinical waste bag that has been clearly labelled 'Waste Human Tissue for Incineration'.

4.3.2 Any sections that have been floated out in the water bath should be picked up with a pair of forceps and wiped on a small piece of medi-wipe tissue and discarded in the same plastic bag.

4.3.3 Sections or blocks of animal tissue MUST NOT be disposed of in the same designated human material clinical waste bag, sharps bin or burn bin.

4.3.4 Bags, sharps bins and burn bins should be tagged and taken to clinical waste bin in local disposal areas for incineration.

4.4 Tissue sections or cytology specimens on glass slides

4.4.1 All relevant material including whole or part cells mounted onto glass slides should be discarded in a yellow sharps bin labelled 'Waste Human Tissue for Incineration'.

4.4.2 Slides prepared with tissue or cells from animals MUST NOT be disposed of in the same designated human material clinical waste sharps bin.

4.4.3 The sharps bin must not be filled to the extent that it becomes heavy to lift.

4.4.4 Sharps bins should be tagged and either taken to departmental disposal areas or collected in accordance with local safety regulations (MAN-22 and Health and Safety SOP-183).

4.5 Disposable equipment

4.5.1 All equipment that has been in contact with relevant materials including scalpels, microtome blades, phlebotomy disposables, disposable gloves, must be disposed of via the appropriate route.

4.5.2 Sharps must be placed into yellow, designated sharps bins.

4.5.3 Other disposable equipment must be processed in accordance with University safety rules (MAN-22) to minimise the infection hazard before being placed in designated yellow clinical waste bags or sharps bins as appropriate.

4.6 Disposal Records and Documentation

4.6.1 Human Tissue waste requires a certificate of destruction for waste disposal records These are not routinely supplied and therefore the correct sections referring to Human Tissue must be completed on the laboratory waste record at the time of tagging the waste to specifically requested disposal. Evidence of disposal must be held by the PI with the study files and details recorded on the sample tracking log.

4.6.2 The clinical waste tag number along with the Study number must be communicated to the Clinical Waste Contract Manager who will request a certificate of destruction from the waste collector.

4.6.3 This certificate of destruction will be passed to the person requesting the information and must be filed with the study documentation.

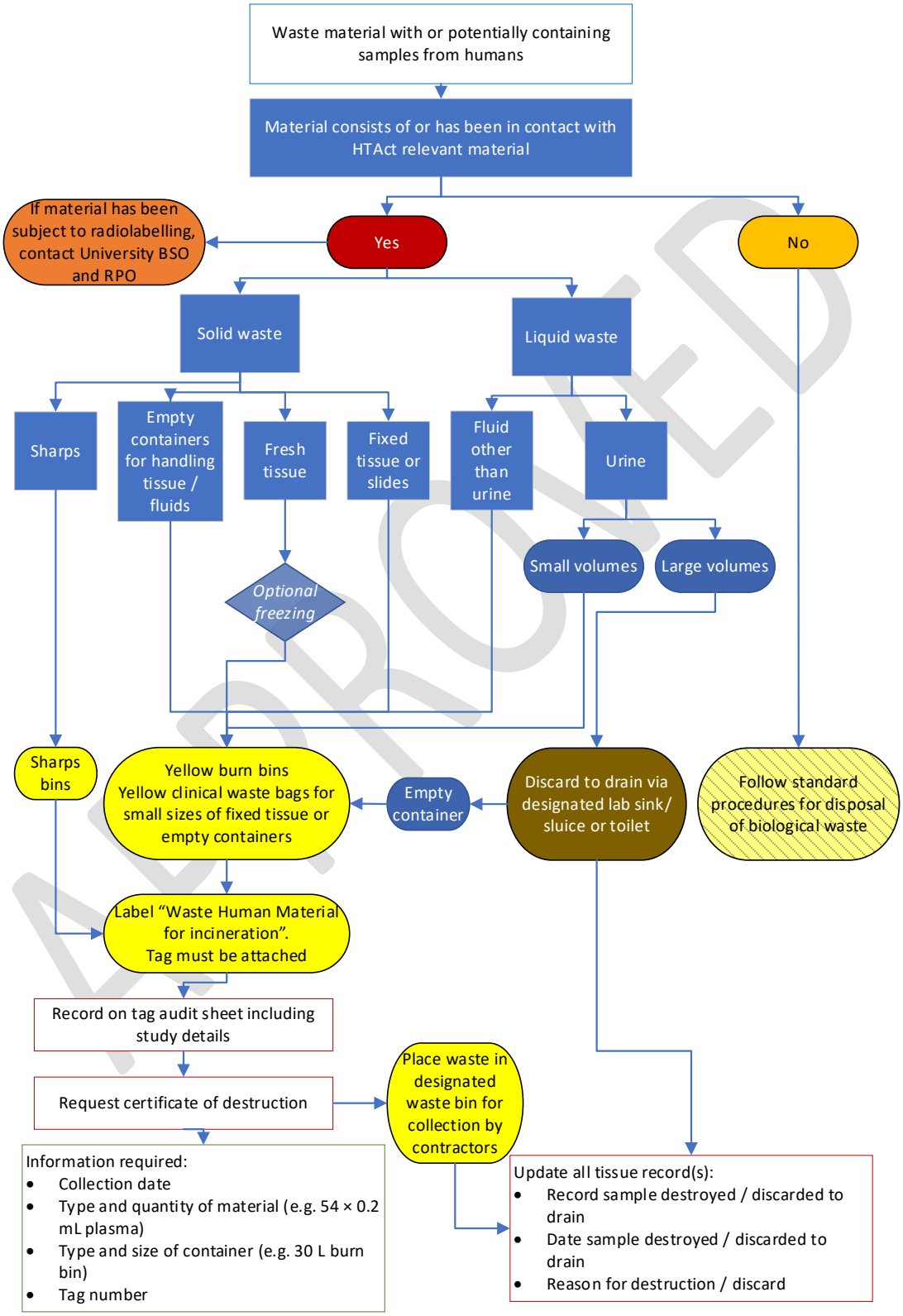
4.6.4 For disposal of large quantities of urine (several litres) from healthy volunteers, a designated and clearly labelled disposal waste systems for surplus biological waste in the laboratory must be used. Suitable options to discard to drain are:

- Use of a designated laboratory sink with plenty of running water.
- Use of a sluice with plenty of running water.
- Use of a flushable toilet.

The dates, volumes and study number of disposal must be recorded.

4.6.5 Databases must be annotated to show that the sample has been destroyed, the reason, date of destruction and waste tag number, which connects to the certificate

4.7 Waste processes:



5. GLOSSARY OF TERMS

HTA	Human Tissue Authority
HTAct	Human Tissue Act
SOP	Standard Operating Procedure

6. 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

7. REFERENCES

- Health Technical Memorandum 07-01 – Safe management of healthcare waste, Department of Health
- HTA Code of Practice and Standards: Code E, Research

8. TRAINING

All personnel disposing of human tissue must have read and understood this SOP in relation to the areas they are working in. All individuals must complete the local laboratory induction which includes training on this SOP.

9. REVISION HISTORY

Version number	Revision details	Author	Date