Human Samples in Research Standard Operating Procedure 6
Disposal

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Revision Chronology:	Effective date:	Reason for change:
HS6.02	13 December 2010	Clarification of University policy – QMS applies to all human samples. Creation of the role of Administrative Officer, Deputy DI and changes to the role of PD. Reorganisation of Biological Sciences to form the School of Life Sciences.
HS6.03	10 January 2012	Changes in staff, room numbers and external links.
HS6.04	25 February 2015	Changes to University governance structures relating to human samples.
2.0	14 July 2023	Various updates including changes made for clarity, accuracy and readability, removed sections duplicated in each SOP (to be included in Quality Manual), added reference to University's agreed three-tier 'risk-based' approach, links to HTA guidance updated as appropriate.
2.1	24/2/2024	Links updated

NOTE*:* SOPs will be reviewed on a 2-yearly schedule.

The definitive version of this SOP is available here: https://warwick.ac.uk/services/ris/research-compliance/human-tissue/hereatwarwick/sop/

Printed copies are outside the document control system. Ensure you are using the most up to date version.

Disposal

1. Purpose and scope

The purpose of this Standard Operating Procedure (SOP) is to ensure that all staff and students understand the requirements and procedures for the disposal of human samples, covered by the Human Tissue Act 2004 (HT Act), the Human Tissue Authority's (HTA) Codes of Good Practice, the University's HTA licence for research and the University's Quality Management System for the governance, storage, use and disposal of human samples for research.

2. Background

This SOP forms part of the University's Human Samples in Research Quality Management System (QMS). All research involving human samples at the University of Warwick must comply with this Quality Management System.

The University requires that all human samples defined as relevant material by the HTA and held at the University for Research shall meet the standards of quality management set out in its standard operating procedures. For the avoidance of doubt, this includes any cellular human material, regardless of whether it has current REC approval, unless it is a cell line that has been passaged at least three times. A risk-based approach will be applied.

This SOP has been produced in accordance with the HT Act which came in to force on 1 September 2006, and should be read in conjunction with the HTA's *Codes of Practice*, available at: https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation

The HT Act regulates disposal of human tissue (excluding gametes and embryos), including imported tissue, following its use for research (a scheduled purpose).

The HT Act makes it lawful to treat as clinical waste any material that has come from a living person who was:

- in the course of receiving medical treatment,
- undergoing diagnostic testing, or
- participating in research.

The HT Act also states that material no longer used, or stored for use, for any scheduled purpose can be dealt with as waste.

There may be additional requirements and considerations relating to the disposal of existing unidentifiable holdings, identifiable but unclaimed samples, organs and fetal material not specifically included in this SOP. Staff should consult with the DI in such cases, who will seek advice directly from the HTA, as appropriate.

3. Responsibilities

The Registrar (as the Licence Holder's Representative) and the Designated Individual (DI) are responsible for ensuring that appropriate procedures are in place, and that staff and students involved in research using human samples are appropriately informed and trained and that the conditions of the licence are complied with relating to the disposal of human samples.

The Lead Investigator (or the person delegated by the Lead Investigator, and appropriately trained), as custodian of the samples, is responsible for understanding and following the appropriate procedures and practices, attending training and updating, and complying with the conditions of the University's Human Samples in Research Quality Management System.

Individual researchers are responsible for ensuring that they dispose of material in accordance with this SOP, and that they document clearly, accurately and promptly, the date, reason and method for disposal.

Persons designated are responsible for providing advice about disposal procedures and ensuring that appropriate processes are used by the technical teams responsible for waste management.

Heads of Department are responsible for ensuring that members of their department comply with the SOPs for working with human material.

The Human Samples Steering Group (HSSG) is responsible for reviewing all SOPs. Substantial amendments to existing SOPs, the creation of new SOPs and changes to the Quality Management System, will require approval by the University's Genetic Modification and Biosafety Committee (GMBSC). The DI will sign each SOP following approval by GMBSC.

4. Policies

4.1 In keeping with its HTA Research Licence, the University has standard procedures for disposal of all human samples considered relevant material by HTA (see https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004) .

4.2 Any member of staff or student disposing of relevant human material must be appropriately trained, see HSR SOP 7 Training.

4.3 Dignified treatment and separate disposal are the minimum considerations for the disposal of relevant human samples. This means disposal should be carried out separately from other clinical waste, but it is not necessary for each human sample to be disposed of separately.

4.4 Human samples must be disposed of observing due care and respect for the material at all times, and the consent given, the wishes of the donor and/or their family or other appropriate individual, in the case of samples from the deceased, where appropriate. Wishes of a deceased person, or those close to them, regarding the method of human sample disposal must be reasonable and lawful.

4.5 Some patients/donors may wish to retain tissue samples or make their own arrangements for disposal. Such requests should be considered on a case-by-case basis, and with advice from the DI where appropriate, assessing the risk to the patient/donor and others. Patients/donors should be given sufficient information at the point of consent to allow them to make an informed decision.

4.6 Any specific requirements relating to the disposal of human samples agreed at the time of their acquisition, e.g. in a Material Transfer Agreement, must be observed.

4.7 Tissue may need to be disposed where, for example, the consent does not permit its broad use for research beyond the end of the project for which it was collected, or if consent has been withdrawn. Such disposal must be in accordance with the guidance set out in the HT Act. This is

described clearly at: https://www.ukri.org/wp-content/uploads/2021/11/MRC-301121-ResearchHumanTissueAct2004-DisposalSummary.pdf

5 Procedures

5.1 Disposal of human samples

5.1.1 Personnel responsible for disposing of human samples must be appropriately trained, and demonstrate due care and respect for the material.

5.1.2 Disposal should be in keeping with the consent associated with the sample.

5.1.3 Depending upon the nature of the project, disposal of human material may occur when individual samples are used up, or of surplus material not required for the research project, or batchwise, for example at the end of a project, or if consent or ethical or MTA approval runs out and has not been renewed.

5.1.2 It is the responsibility of the Lead Investigator or their appropriately trained delegate, to complete the Human Samples Disposal Form (see Appendix 1) , sending it to hta@warwick.ac.uk, and to obtain the approval of the DI prior to disposal of a batch of samples, or to notify the DI that a number of individual samples collectively have been used up. The Human Samples Disposal Form will be filed in the disposals folder on the shared drive by the DI or Research Governance Coordinator.

5.1.3 All human samples in Tiers 1 and 2, to be disposed of should be collected in the rigid yellow containers marked for the disposal of human material. This includes formalin-fixed blood which must not be autoclaved (see Appendix 2). Relevant material (Tier 1) should be kept in separate bags or boxes from any other material for disposal.

5.1.4 Human samples will be disposed of by incineration. This includes surplus material from human samples, such as:

- tissue fragments trimmed from the tissue sample before it is processed for histology;
- tissue in sections trimmed from a wax-embedded block before the usable sections are cut;
- unrecoverable bodily material that is washed out of the tissue during processing
- Residual material left in tubes or on pipette tips

5.1.5. Note that, for safety reasons, formalin-fixed samples requiring disposal must be collected in a separate yellow clinical waste bag or rigid yellow box and be disposed of separately from all other clinical waste since this material cannot be autoclaved.

5.1.6 It is the responsibility of the Lead Investigator or their appropriately trained delegate to update the Sample Register following the disposal of any material. For further information on sample tracking and the data requirements for the Sample Register, see HSR SOP 4.

5.1.7 When samples require disposal and there is no regular collection of clinical waste (e.g. routine weekly collection), a clinical waste collection should be requested through the technical services team for the area.

5.2 Disposal following an adverse event or catastrophic equipment failure

Following an adverse event or catastrophic equipment failure, where human samples have been severely damaged or destroyed, the Lead Investigator must complete the Human Sample Adverse Event/Incident Report and submit it to the DI, in accordance with the HSR SOP 5 Adverse Events. Where the samples have been rendered unfit for use and require disposal, the Lead Investigator must ensure that the Human Samples Disposal Form (Appendix 1) is completed and submitted to the DI for authorisation to dispose of the damaged material. The DI will take responsibility for disposal in such circumstances, following an investigation.

6. Training

All those involved in research involving human samples are required to read this SOP and to understand how its requirements relate to their research. A record of this should be kept This should be recorded in the Personal Training Portfolio (PTP) on the Working with Human Samples sign-off form, in accordance with the HSR SOP 7 Training.

7. Advice and guidance

Further advice on the disposal of human samples and the provisions of this SOP may be sought from the DI. The DI may seek advice directly from the HTA and the University Safety Officer when as appropriate.

8. Monitoring and audit

Regular monitoring of the effectiveness of the implementation of this SOP will be undertaken by the DI and/or others nominated by the DI. In addition, audits may be undertaken by the DI, the University's Internal Audit Service or the HTA, in accordance with HSR SOP 8 Audit.

List of Abbreviations

HTA	Human Tissue Authority
HT Act	Human Tissue Act 2004
DI	Designated Individual
HSSG	Human Samples Steering Group
PD	Persons Designated
PI	Principal Investigator
R&IS	Research & Impact Services
SOP	Standard Operating Procedure

Templates/Associated Documents

Appendix 1: Checklist of documentation required prior to acquisition and import of human material in Warwick Tiers 1 and 2.

Appendix 2: Authority to Import Human Samples

Appendix 3: Checklist of documentation required prior to export of human material in Warwick Tiers 1 and 2.

Appendix 4: Authority to Export Human Samples

Appendix 1

Human Samples Disposal Form

To be completed by the Lead Investigator or their appropriately trained delegate

Project Details	
GMBSC Project Number	
Project title	
Ethical Approval Number	
Lead Investigator or Person Responsible for the samples	
Disposal Details	
Proposed date of disposal	
Type and amount of sample (e.g. urine; plasma) for disposal	
Quantity of samples	
Tissue sample numbers (i.e. unique identifiers)	
Method of Disposal (see HSR SOP 6)	
Reason for disposal *(include reference to consent , wishes of donor, or agreement on sample acquisition in e.g. MTA, as appropriate)*	

I confirm that the information above is accurate and complete and that Sample Register will be updated following completion of the disposal of the human samples:

Name of Lead Investigator or appropriately trained delegate:.....

Signature:..... Date:.....

I authorise disposal of these human samples:

Signature of Designated Individual:..... Date:.....

Appendix 2

Disposal of formalin-fixed blood samples

Blood samples may be treated with formalin (40% formaldehyde solution) to neutralise any harmful microorganisms or viruses that may be present. It may also be used to fix the cells so they can be stored prior to analysis. Due to the hazards associated with heating formaldehyde, any such samples must not be autoclaved due to the potential harm to personnel, visitors and equipment.

Hazards

Formaldehyde

The Maximum Exposure Limit (MEL) for formaldehyde is 2ppm for short-term exposure. It is mandatory to ensure that the MEL is **never** exceeded and that exposure is kept as low as practicable.

- To prevent explosion, conditions should be humid and warm [above 65% relative humidity and above 20°C].
- To prevent the production of harmful vapours, samples should not be heated above 50°C.
- To prevent the formation of harmful products, formaldehyde must be kept away from compounds that contain chlorine.
- The procedure must only be carried out by suitably trained and authorised personnel who are members of University staff.

Formalin-fixed samples requiring disposal must be collected in a separate yellow clinical waste bag and be disposed of separately from all other clinical waste.