King's College London
Human Tissue Authority Licensed Laboratories

Standard Operating Procedure

Title: Disposal of surplus and unusable human material

Purpose
The purpose of this SOP is to describe the disposal of all waste human relevant material (as defined by the Human Tissue Act 2004) pertaining to research purposes, human applications and public display.

Scope
The scope of this SOP is to describe the disposal of waste human material. This includes any material containing whole or part cells. It does not include hair, nails, cell lines or cell derivatives such as DNA or RNA

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

Document Detail	
Reference Number	KCL HTA101/Disposal
Version	7.0
Effective From	Jan 2009
Review Date	Feb 2013/ May 2015/ July 2017/Sept 2019/ Nov 2021/ Aug 2024/Sep 2026
Author	Dr Cheryl Gillett
Approved By	KCL HTA Governance Group [30-Sep-2024]

Revision status

Each document has an individual record of amendments. The current amendments are listed below. The amendment history is available from the document control system

On issue of revised or new pages each controlled document should be updated by the copyholder.

Amendment Number: Date	Version no. Discarded	Insert Version no	Page	Section(s) involved	Amendment
1. 21/1/09	1.0	1.1	3-4	3.1.4, 3.2.4, 3.3.3, 3.4.2	Segregation of animal/non-human clinical waste prior to disposal
2. 16/2/10	1.1	2.0	1 4 5 5	Purpose, Scope 3.5 3.6 4	Additional information included. New section added. New section added HTA update
3. 28/5/13	2	3.0	3 & 5	3.1.1 & 3.6.1	Use of Wiva bins for larger specimens
4. 08/6/15	3	4.0	5	4	Updated list of HTA relevant material
5. 22/9/17	4.0	5.0	5	4 8	Disposal record details added Appendix A added
6. 15/08/2022	5.0	6.0	3 3&4 5 6	1.1 3.1 & 3.2 4 5	Updated H&S document Additional disinfection requirement Removed requirement for separate disposal log HTA relevant material updated
7. 30/09/2024	6.0	7.0	3 5	3.4 3.6	Inclusion of Wiva bins Inclusion of large research specimens

Any minor amendment must be handwritten on the SOP without obscuring existing text. An asterisk should be placed in the adjacent margin to highlight the alteration. Alterations should be signed and dated by either the person designated or nominated individuals and then forwarded to the document controller. The SOP must be retyped, authorised and reissued as soon as possible. Amendments requiring immediate action should be dealt with in the same way but highlighted as high priority. Major changes must result in the immediate review of the procedure Document amendment does not replace the review process.

1 Responsibilities

1.1 User

It is the responsibility of the user to ensure that:

(i) They adhere to the disposal of human relevant material procedure as outlined in this SOP in addition to the KCL Health & Safety Services issued, “SPR040, Biological Safety Procedure”.
(ii) They are aware of what material is classified as ‘Relevant material’ by the Human Tissue Act 2004 (summarised in Section 4).
(iii) Waste relevant material should be treated with respect to the consenting donor.
(iv) Any instructions from the donor on method of disposal are adhered to
(v) They inform their line manager and HTA Person Designated immediately of the failure of material being disposed of in a correct manner.

2 Materials

2.1 Equipment

Yellow Clinical Waste bag labelled as “Waste Human Tissue for Incineration”
Identifying tags
Yellow Sharpsafe bins
Yellow Wiva bins

3 Procedures

3.1 Fresh/Unfixed Cells or Tissue

3.1.1 Fresh or unfixed relevant material may be disinfected where practical and safe to do so before being placed into designated yellow clinical waste bags or Wiva bin if a larger specimen.
3.1.2 Where there is a known infection risk, fresh samples must be disinfected prior to disposal.
3.1.3 If it is not practical or safe to disinfect the relevant material then it may either be placed in a designated yellow clinical waste bag and frozen for short term storage or placed directly into a Wiva bin.
3.1.4 Samples of unfixed relevant material that have frozen for longer-term storage may be placed directly into a Wiva bin.
3.1.5 Empty specimen containers that have been in contact with the specimen and, therefore have residual cells, should be disinfected before being discarded in the designated yellow clinical waste bags.
3.1.6 Any Wiva bin used for disposal of relevant material must be labelled “Waste Human Material for incineration.”
3.1.7 Any human material, which becomes attached to equipment during tissue processing (eg cryostat chamber) should be removed with forceps or a small amount of medi-wipe tissue and discarded in the designated bag.
3.1.8 Animal tissue and other waste **MUST NOT** be disposed of in the designated human material clinical waste bag, sharpsafe or Wiva bin.
3.1.9 Bags should be tagged and taken to clinical waste bins in local disposal areas.

3.1.10 Relevant material, which has a high biohazard risk, should be processed in accordance with College safety rules to minimise risk before being placed in the designated yellow clinical waste bag.

3.1.11 Relevant material that has been subjected to any radiolabelling procedure must still be segregated from non-relevant and animal material. Material can then be discarded in accordance with local safety rules for disposal of radioactive material.

3.2 Body Fluids

3.2.1 All acellular components of bodily fluids (eg plasma, filtered urine) can be discarded in accordance with local safety rules.

3.2.2 Cellular components can be neutralised before leaving College property where it is safe and practical to do so. Unwanted blood fractions and the contents of open tubes can be neutralised with disinfectant before either being discarded down the 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 neutralised by autoclave before disposal in a sharpsafe bin. If it is not safe or practical to do so, tubes containing cellular components may be placed directly into a Wiva bin labelled "Waste Human Material for incineration."

3.2.3 Where there is a known infection risk, body fluids or residual cellular components must be disinfected prior to disposal.

3.2.4 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 sharpsafe bin to avoid risk of injury or spillage.

3.2.5 Animal tissue and other clinical waste **MUST NOT** be disposed of in the designated human material clinical waste bag or sharpsafe bin.

3.2.6 Bags should be tagged and taken to clinical waste bins in floor disposal areas.

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

3.2.8 Relevant material, which has a high biohazard risk, should be processed in accordance with College safety rules to minimise risk before being placed in the designated yellow clinical waste bag or sharpsafe bin.

3.3 Fixed, paraffin-wax embedded tissue

3.3.1 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'.

3.3.2 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 paper tissue and discarded in the same plastic bag.

3.3.3 Sections or blocks of animal tissue MUST NOT be disposed of in the designated human material clinical waste bag or sharpsafe bin.

3.3.4 Bags should be tagged and taken to clinical waste bin in local disposal areas.

3.4 Tissue sections or cytology specimens on glass slides

3.4.1 All relevant material including whole, or part cells mounted onto glass slides should be discarded in a Wiva or sharpsafe bin labelled 'Waste Human Tissue for Incineration'.

3.4.2 Slides prepared with tissue or cells from animals MUST NOT be disposed of in the designated human material waste bin.
3.4.3 The Wiva or sharpsafe bin must not be filled to the extent that it becomes heavy to lift.
3.4.4 Wiva and Sharpsafe bins should be tagged and either taken to floor disposal areas or collected in accordance with local safety regulations

3.5 Disposable equipment

3.5.1 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.
3.5.2 Sharps must be placed into yellow, designated sharpsafe bins.
3.5.3 Other disposable equipment must be processed in accordance with College safety rules to minimise the infection hazard before being placed in designated yellow clinical waste bags or sharpsafe bins as appropriate.

3.6 Museum, Anatomical Examination Preparations and Large Research Specimens - unfixed, screened body parts and fixed whole or portions of organs

3.6.1 All relevant material including body parts, whole organs, dissected organs or trimmings should be placed in designated Wiva bins and the label details completed. Yellow clinical waste bags **MUST NOT** be used.

3.6.2 Specimen containers that have been in contact with the specimen and, therefore have residual cells, should also be disinfected before being discarded in separate designated yellow clinical waste bags.

3.6.3 Animal tissue and other non-clinical waste **MUST NOT** be disposed of in the designated human material clinical waste bag or sharpsafe bin.

3.6.4 Bags should be tagged and taken to clinical waste bins in local disposal areas. Where large volumes of material are to be discarded, the whole bin can be tagged rather than individual bags.

3.6.5 All relevant records including daybooks, database, indexes to be amended and removal date recorded.

4 Disposal Records and Documentation

Full traceability of all relevant material which is removed, used, stored and disposed of is a basic tenet of the Human Tissue Act. Sample logs must be annotated to show that the sample has been destroyed and include the reason and date of destruction. Alternatively, a separate disposal record may be kept using a Human Tissue Disposal Form (Appendix A).

5 Relevant Material (taken from HTA website, updated July 2022)

Materials classified in the following list as relevant material are done so subject to the following general caveat that they are relevant material except where:
• They have divided or been created outside the human body

• They have been treated, processed, or lysed through a process intended to render them acellular. This would include the freezing or thawing of cells only where that process is intended to render the material acellular.

* While outside the definition of relevant material for the purposes of the HT Act, these materials fall under the remit of the Human Fertilisation and Embryology Act 1990 and are regulated by the Human Fertilisation and Embryology Authority (HFEA).

Material considered to be 'relevant material'

Nail (from deceased person)
Bile
Blood
Nasal and bronchial lavage
Bone marrow
Non-blood, derived stem cells (i.e. derived from the body)
Bones/skeletons
Non-fetal products of conception (i.e. the amniotic fluid, umbilical cord, placenta and membranes)
Brain
Breast milk
Organs
Pericardial fluid
Buffy coat layer (interface layer between plasma and blood cells when blood is separated
Platelets
CSF (cerebrospinal fluid)
Pleural fluid
Cystic fluid
Primary cell cultures (whole explant/biopsy present)
Pus
Saliva
Skin
Faeces
Fetal tissue (material relating to early pregnancy loss or termination)
Sputum (or phlegm)
Fluid from cystic lesions
Stomach contents
Hair (from deceased person)
Teeth
Tumour tissue samples
Joint aspirates
Umbilical cord blood stem cells
Urine
Mucus

Material not considered to be 'relevant material'

Antibodies
Nail (from living person)
Breath condensates and exhaled gases

Plasma (Please note: Depending on how plasma is prepared and processed, it may contain small numbers of platelets and other blood cells. If any of these cells are present, then the plasma must be regarded as relevant material)
Cell lines
Cells that have divided in culture
DNA
Eggs (ova)
RNA
Embryonic stem cells (cells derived from an embryo)
Embryos (created outside the body)
Sebum
Extracted material from cells e.g. nucleic acids, cytoplasmic fractions, cell lysates, organelles, proteins, carbohydrates and lipids.
Serum
Sperm cells (spermatozoa)
Gametes
Sweat
Hair (from living person)
Lysed cells

Appendix A

Human Tissue Disposal Form

To be completed by the person undertaking the disposal of relevant material. This document must be kept by the Principle Investigator or Person Designate.

Human Tissue Disposal Form	
REC number (if applicable)	
Project / Collection name	
Person Designate contact details	Name: Email: Phone:
Unique sample number(s)	
Type of sample(s)	
Reason for disposal	
Date of disposal	
Total amount of tissue to be disposed of	
Method of disposal	
Name and contact details of the person authorising disposal	Name: Email: Phone:
Name and contact details of the person undertaking the disposal	Name: Email: Phone: