Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Disposal of Human Tissue**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
FMS&LS/SOP/003/002	04/10/12	Rewrite because of integration to Research Governance	v1.0
V 1.0	27 June 2013	Change to Clinical Waste Packaging Regulations	V2.0
V 2.0	08 August 2013	Change to reflect practices of disposal contractor	V 3.0
V 3.0	06 October 2014	Periodic review. Queen's Online replaced by Research Governance Website included on cover page.	V 4.0

1. Purpose

This Standard Operating Procedure (SOP) describes the process for disposal of human tissue as required by the Human Tissue Act 2004 (HT Act).

2. Introduction

The HT Act came into force on the 1 September 2006 and provides a framework for regulation of research involving the removal, storage, use and disposal of human tissue. The Act requires that human tissue, defined as relevant material, is disposed of appropriately. The disposal requirements may vary depending on whether or not the tissue is from the living or the deceased. Research participants, or their relatives, should be made aware of how their tissue will be disposed of as part of the consent process. The Human Tissue Authority (HTA) code of practice 5 'disposal of human tissue' provides guidance on the standards expected for the disposal of human tissue.

3. Scope

This SOP applies to all members of University staff; both academic and support staff as defined by Statute 1 and including honorary staff and students who are responsible for the disposal of relevant material in the areas licensed for research by the HTA at Queen's University Belfast.

Note: Human tissue samples collected as part of a clinical trial of an investigational medicinal product (CTIMP) or samples acquired from the Northern Ireland Biobank will have their own procedures and requirements and should not follow this SOP.

4. Responsibilities

4.1 Designated Individual

The Designated Individual (DI) is responsible for ensuring that appropriate disposal procedures and practices are in place as required by the terms of the HTA licence.

4.2 Person Designated

The Person Designated (PD) is responsible for providing advice and guidance on appropriate disposal procedures and practices in their area as required.

4.3 Chief Investigator or custodian of the samples

The Chief Investigator (CI) or custodian of the samples is responsible for ensuring all human tissue is disposed of appropriately in accordance with the requirements of HT Act, that disposal records are maintained and that the Human Tissue Register is updated to reflect any disposal.

4.4 Researcher or other support staff

The researcher or other support staff delegated the task of disposing of human tissue must ensure that the disposal is carried out in accordance with this SOP and that appropriate disposal records are maintained.

5. Procedure

5.1 General

The HT Act defines relevant material as material that has come from the human body and consists of or includes human cells (see HTA website http://www.hta.gov.uk/ for a full list of relevant material).

Human tissue must be treated in a dignified manner and disposed of separately to other waste.

When human tissue is acquired from another establishment, the disposal requirements stipulated in the Material Transfer Agreement (MTA) or Service Level Agreement (SLA) must be adhered to.

All health and safety requirements with regards to the disposal of human tissue (ie for hazardous material) must be followed. The University's Biological Safety Guidance and Chemical Safety Policy provide further information (http://www.qub.ac.uk/directorates/HumanResources/OccupationalHealthandSafety/HealthandSafetyPolicy/PolicyandGuidance/). Risk assessments must be completed for all research activities involving human tissue, including disposal, to minimise the risk of contamination and protect the health and safety of staff, students and visitors.

5.2 Disposal Procedure

5.2.1 Primary Packaging

All relevant material for disposal must be contained in an appropriate clinical waste bin as detailed in **(Appendix 1)** unless burial or cremation is deemed more appropriate.

Anatomical waste should be placed in a red-lidded bin. Anatomical waste is defined as relevant material that is a recognisable (for example a whole eye would be classed as anatomical waste whereas a sample of vitreous humour would not).

All clinical waste bins containing relevant material must be destined for incineration. Care must be taken as orange-lidded 60 litre bins are heat-treated and sent to deep land fill. However orange-lidded sharps bins are incinerated and would be suitable for the disposal of relevant material.

Each clinical waste bin **must**:

- Only contain human tissue or material contaminated with human tissue;
- Be assembled according to the manufacturer's instructions;
- Be labelled "HTA relevant material only";
- Be signed and dated by the person assembling/closing the container;
- Have a traceable label.

Each clinical waste bin **must not**:

- With the exception of 'sharps' bins be used for the disposal of sharps;

- Be filled more than ¾ full;
- Be placed within a yellow/orange bag.

5.2.2 Disposal of primary packaging containing human tissue

(i) Bins should be permanently sealed and tagged then placed in a designated collection area;
(ii) Designated areas must not be within publicly accessed areas or food preparation areas;
(iii) Designated areas must be well ventilated;
(iv) At the point of origin, human tissue destined for disposal should be stored no longer than necessary and in appropriate conditions.

Guidelines on clinical waste packaging for disposal are given in Appendix 1.

5.3 Disposal of tissue from the deceased

Tissue samples from the deceased should be handled in accordance with the wishes of the deceased person or their relatives when the expressed method of disposal is reasonable and legal.

Human tissue removed from the deceased can only be used for research purposes if appropriate informed consent is in place. Consideration should be given to disposal arrangements at the time of obtaining consent and the disposal procedures explained to the individual providing the consent.

Disposal options available for tissue from the deceased include incineration, cremation or burial.

5.3.1 Existing holdings

The term existing holdings refers to human tissue collected prior to the implementation of the HT Act on the 1 September 2006. Existing holdings may include blocks, slides, organs and bones.

(i) Unidentifiable existing holdings

The HTA consider existing holdings of tissue from the deceased to be unidentifiable if:

- There is no label or identification mark affixed to the organ or tissue;
- There is a label or identification mark but this cannot be linked to any existing record;
- There is a label or identification mark which can be linked to a record but identification requires a link with records or registers that no longer exist

Unidentifiable existing holdings from the deceased may be disposed of by incineration, burial or cremation as appropriate.

(ii) Identifiable existing holdings

Identifiable existing holdings for which relatives are in contact with the University should be retained until such times as the relatives can make their wishes clear.

If it is not possible to make contact with a relative or if contact is made but subsequently lost identifiable existing holdings may be considered to be unclaimed and disposed of by incineration, burial or cremation as appropriate.

5.4 Disposal of tissue from the living

Human tissue taken from the living, including tissue no longer being stored for a scheduled purpose (ie research), should normally be disposed of by incineration and in accordance with the disposal procedure described under 5.2. There may be practical exceptions which limit incineration as a disposal method for some forms of relevant material (eg 24 hour urine collections). If unsure, researchers are advised to consult with the PD for their area on the most appropriate disposal method.

5.4.1 Surplus human tissue

Surplus human tissue acquired from the living as a result of participating in research, receiving medical treatment or undergoing diagnostic testing can be treated as waste and should be disposed of by incineration in accordance with the disposal procedure described under 5.2. Surplus human tissue also includes tissue fragments trimmed from the sample before it is processed for histology and tissue sections trimmed from wax-embedded blocks prior to use.

5.4.2 Existing holdings

Identifiable and unidentifiable human tissue removed from the living prior to the implementation of the HT Act on the 1 September 2006 should be disposed of by incineration and in accordance with the disposal procedure described under 5.2.

5.5 Disposal documentation/records

The following information must be recorded in local records for the disposal of relevant material:

- Date of disposal;
- Name of person undertaking the disposal;
- Name of the CI/custodian of the samples;
- Unique sample identification number (or series);
- Method of disposal;
- Reason for disposal (eg end of study, withdrawal of consent).

A suggested disposal form template is provided in Appendix 2. The CI is responsible for ensuring the Queen's Online (QOL) Tissue Register is updated following disposal of any relevant material.

6. References

Human Tissue Authority Code of practice 5 – Disposal of Human Tissue
http://www.hta.gov.uk/_db/_documents/Code_of_practice_5_-_Disposal_of_human_tissue.pdf (last access October 2014)

Human Tissue Authority definition of relevant material
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm (last accessed October 2014)

QUB Occupational Health and Safety
http://www.qub.ac.uk/directorates/HumanResources/OccupationalHealthandSafety/HealthandSafetyPolicy/PolicyandGuidance/ (last accessed October 2014).

7. Appendices

Appendix 1	Guidelines on clinical waste packaging for disposal List
Appendix 2	Disposal form template

Guidelines on Clinical Waste Packaging for Disposal

Freezers in the MBC store are for waste that is likely to undergo putrefaction. The empty bins in the freezer should be either labelled "HA" for receiving human anatomical waste or "VA" for receiving animal anatomical waste by the first user of a particular bin. Alternatively the tissue could be formalin fixed by appropriately trained personnel.

Every container should be uniquely labelled (lab number and building, ie 135WMB) and identifiable and all the relevant details recorded in the clinical waste log book.

The Contractor will not accept waste in any other type of container such as clinical waste plastic bags or "home-made" containers.

Type of clinical waste bin	Contents	Waste category code
60 litre Red-lidded burn bin Destination: Incineration	Human tissue/anatomical waste	HA Additionally, bin must be labelled **"HTA Relevant Material Only"**
	Animal tissue/anatomical waste	VA
60 litre Yellow-lidded burn bin Destination: Incineration	Laboratory waste or other waste not suitable for heat treatment*	HI
60 litre Orange-lidded burn bin Destination: Heat-Treatment & Deep Land Fill	Infectious or potentially infectious clinical waste contaminated with bodily fluids and/or free fluids. Must NOT contain HTA relevant material*	HT or HL
Orange Bag Destination: Heat-Treatment & Deep Land Fill	Infectious or potentially infectious soft clinical waste contaminated with bodily fluids e.g. gloves & tissues. Must NOT contain HTA relevant material*	HT or HL
60 litre Purple-lidded burn bin Destination: Incineration	Clinical waste contaminated with cytotoxic and cytostatic material (EtBr gels etc)	HY
Orange lidded sharps bins Destination: Heat-Treatment & Deep Land Fill	Laboratory clinical sharps	HT
Orange lidded sharps bins **WHEN SEALED, PLACE IN 60L RED LIDDED HA BIN** Destination: Incineration	Laboratory clinical sharps contaminated with human waste	HA or HAS Additionally, bin must be labelled **"HTA Relevant Material Only"**

[1]Please note the 60 litre burn bins must not be used for sharps – they are thin gauge plastic and are not designed to contain sharps.

[2]HTA relevant waste material from the living must be disposed of by incineration only. No HTA relevant waste materials may disposed of by any route that culminates in land-fill. (HTA relevant waste material from post mortem must be disposed of in accordance with the consent given and/or the wishes those giving consent on behalf of the deceased so long as lawful).

Disposal Form Template

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Appendix 2

Date: _____

Name of person for whom undertaking disposal:

_____

Number/quantity of samples to be disposed:

_____

Sample identifiers (or series):

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Method of disposal:

_____

Reason for disposal:

_____
_____
_____

Signature: _____ Print name: _____

Signature: _____ Print name: _____