The Oxford Centre for Diabetes, Endocrinology and Metabolism

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Disposal of Human Tissue and Relevant Material (Research)

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Update History

Version	Date	Reason for update	Updated/reviewed by :	Date next review due
1	Dec 2008	New SOP (changes suggested by OCDEM SAC implemented before ratification in Jan 2009)	Author: SMH	Jan 2011
2	July 2011	Changes in format, personnel and minor changes to wording to bring in line with Sep 2009 Code of Practice.	SMH	July 2013
2.1	23 August 2015	Links updated. HoD added	SMH, accepted by DI and HoD (Chair of SAC)	August 2017

Contents

Update History 2
1 Background 4
2 -Purpose 4
3 Scope 4
4 Definitions 4
4.1 Designated Individual and Persons Designated 4
4.2 Relevant material 4
4.3 Disposal 4
5 Responsible personnel 5
6 Procedure 5
6.1 General Principles 5
7 Patient's wishes 5
8 Tissues removed after death 5
9 Surplus material from tissue samples 5
10 Existing holdings of unidentifiable, and identifiable but unclaimed, tissue 6
11 Disposal within OCDEM 6
12 Audit of disposal 6

1 Background

The Human Tissue Authority (HTA) was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes – such as research, transplantation, education and training – set out in the Human Tissue Act 2004 (HT Act).

The duty to create and maintain proper records starts with the establishment, where the material is removed from the body, or where the material is identified as surplus to requirements for healthcare purposes and is set aside for a scheduled purpose.

The HTA Code of Practice 5 – 'Disposal of Human Tissue', provides practical guidance to those carrying out activities which lie within the regulatory remit of the HTA, and details the standards expected for the disposal of human material.

The HTA Licence granted to OCDEM authorises the storage of relevant material which has come from a human body for a scheduled purpose (Research). Where human tissue/cells have been removed from a human body for research, disposal is required in accordance with the HTA Code of Practice 5.

2 Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure that staff, students and visitors involved in research within OCDEM, which is covered by the HT Act, understand the procedure and mechanisms for the disposal of human tissue.

3 Scope

This SOP applies to all Oxford University staff/students and visitors working within OCDEM who are responsible for the disposal of human tissue/relevant material for research purposes. This SOP aims to ensure the aforementioned are fully trained on the requirements for the disposal of human material under the HT Act and the HTA Codes of Practice and other relevant OCDEM SOPs and policies.

4 Definitions

4.1 Designated Individual and Persons Designated

The Designated Individual is authorised, accepts executive responsibility for, and supervises the activities performed under a licence issued by the HTA; the PDs are available to help the DI in his duties.

4.2 Relevant material

Any material collected from a human body that contains cells. A list of what constitutes relevant material can be found on the HTA website on the 'Relevant material' page. The list of Relevant Materials can also be found on the OCDEM network at: Shared\ Safety\HTA\HTA list of relevant materials.pdf

4.3 Disposal

The act of permanently disposing of, throwing away, getting rid of relevant material previously stored or used for research purposes.

5 Responsible personnel

- The DI is responsible for ensuring compliance with the conditions of the licence issued by the HTA. Neither, the DI or the PD is responsible for the actual disposal of relevant material.
- The Principal Investigator/Research Supervisor is ultimately responsible for ensuring that this SOP is correctly applied in the conduct of research and each researcher also has individual responsibility for applying this SOP when required to do so.
- The OCDEM Safety Advisory Committee is responsible for ensuring that the SOP remains fit for purpose.

6 Procedure

Human tissue is an invaluable resource for research, and disposal should be a last resort.

6.1 General Principles

- Confidentiality must be observed at all times.
- All personnel disposing of relevant material must be fully trained and competent.
- Relevant material must be disposed of with respect. As an absolute minimum tissue identified for disposal should be disposed of separately from other clinical waste.
- Relevant material must be tracked and recorded at all times.
- The HT Act permits the disposal of surplus tissue as waste and should be disposed of by incineration.
- Material taken from the living should normally be disposed of by incineration in accordance with current guidelines.

7 Patient's wishes

Some patients/volunteers may wish to retain tissue samples or make their own arrangements for disposal. Such requests should be considered on a case-by-case basis assessing the risk to the patient and others. Patients/volunteers should be given sufficient information to allow them to make an informed decision.

8 Tissues removed after death

Tissue and organs removed after death should be handled in accordance with any reasonable wishes expressed by relatives or the deceased person, as long as the method of disposal is legal. The time, place and method of disposal must be recorded.

9 Surplus material from tissue samples

Such material should be disposed of as human tissue waste. This includes:

- tissue fragments trimmed from the tissue sample before it is processed;
- tissue in the sections trimmed from a wax embedded block before the usable sections are cut and
- unrecoverable material that is washed out of tissue during cleaning after a tissue biopsy or during processing into a waxed block.

10 Existing holdings of unidentifiable, and identifiable but unclaimed, tissue

An existing holding is material that was obtained before 1st September 2006 and stored for a scheduled purpose; such material may be incinerated.

11 Disposal within OCDEM

- The majority of relevant material holdings within OCDEM (RDM) consist of blood, urine, biopsies, tissue embedded in paraffin blocks, tissue fixed onto microscope slides and tumour samples. The following instructions refer to the disposal of these materials only.
- Only those delegated or instructed by the DI/PD to dispose of material should undertake this task.
- All personnel handling material for disposal under the HT Act should be fully trained on the 'HTA Code of Practice 5: Disposal of Human Tissue' and adhere to University and OCDEM policies, Control of Substances Hazardous to Health guidelines, and OCDEM local rules.
- It is normal practice to dispose of the material held in OCDEM by incineration. This includes surplus material from samples. Samples must NOT be placed in containers that include other clinical or animal waste.
- Suitable containers for incineration are sharps bins suitable for clinical waste (these are yellow bins that have a yellow lid). Microscope slides must be also be placed in these sharps bins. As many of these samples are small, there should be various sizes of small sharps bins available on site.
  N.B. *Clinical waste container colours*: only yellow sharps bins with yellow lids are incinerated by default. Do not dispose of samples in sharps bins with an orange lid.
- The date and method of disposal of the relevant material, and the name of the person undertaking the task must be recorded in the sample database.

12 Audit of disposal

The DI/PD should conduct an audit of disposal records. Any discrepancies should be recorded as an incident and appropriate corrective and preventative actions implemented.