The Oxford Centre for Diabetes, Endocrinology and Metabolism

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Sample logging, storage and tracking for the purposes of research

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Update History

Version	Date	Reason for update	Updated/reviewed by :	Date next review due
1	Jan 2009	New SOP, accepted by OCDEM Lab Managers, 22/1/09	Author: SMH	Jan 2011
1a	Feb 2009	Numbering added to paragraphs	SMH	Feb 2011
2	Apr 2011	Change in format and new Head of Safety. Inclusion if DNA in section 6.3 plus other minor changes in text.	SMH	Apr 2013
2	April 2013	No changes	SMH	April 2015
2.1	22 August 2015	New header and HoD added	SMH, accepted by DI and HoD	August 2017

Contents

1. Background

The Human Tissue Act 2004 (HT Act) sets out a legal framework for the storage and use of human tissue from the living and for the removal, storage and use of tissue and organs from the dead. This includes 'residual tissue following clinical and diagnostic procedures'.

The purpose of the HT Act is to provide a consistent legislative framework for issues relating to whole body donation and the taking, storage and use of human organs and tissue. It makes consent the fundamental principle, underpinning the lawful storage and use of human bodies, body parts, organs and tissue and the removal of material from the bodies of deceased persons. It introduces regulation of other activities like *post mortem* examinations, and the storage of human material for education, training and research. It is intended to achieve a balance between the rights and expectations of individuals and families, and broader considerations, such as the importance of research, education, training, pathology and public health surveillance to the population as a whole.

The HT Act establishes the Human Tissue Authority (HTA) as the regulatory body for all matters concerning the removal, storage, use and disposal of human tissue.

2. Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure that those involved in research covered by the HT Act understand the procedure and mechanisms for the storage of human tissue.

3. Scope

OCDEM has a licence for research and this SOP is to provide assistance to researchers when performing research under the HT Act. This should be read in conjunction with the Human Tissue Authority's Codes of Practice. Code of Practice 5 – Disposal of Human Tissue is particularly relevant to this SOP.

This SOP applies to all University of Oxford staff, students and visitors within OCDEM responsible for the storage of relevant material for research purposes only. No other scheduled purposes are covered in this SOP.

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. Human Tissue and Relevant Material

Any and all constituent part(s) of the human body, other than gametes, which consists of or includes human cells. The HTA Definition of relevant material sets out guidance on what the HT Act refers to as 'relevant material'. The list of Relevant Materials can also be found on the OCDEM network at: Shared\ Safety\HTA\HTA list of relevant materials.pdf.
The 'List of Relevant materials' can also be found on the OCDEM website on the 'Staff Pages' in the Human Tissue Authority folder.

4.3. Storage

To maintain tissue samples under appropriate controlled conditions.

5. Responsible personnel

- The DI is responsible for ensuring compliance with the conditions of the licence issued by the HTA.
- 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 storing human tissue.
- The OCDEM Lab Managers Committee is responsible for ensuring that the SOP remains fit for purpose.

6. Consent

The HT Act requires consent for the removal, storage and use of human tissue for research purposes from both the living and the deceased.

6.1. Exceptions for research in specific circumstances

Tissue from the living may be stored for use and/or used without consent, provided that:

- the material is from a living person and the research is ethically approved by a recognized research ethics committee;
- the tissue is anonymised such that the researcher is not in possession of information identifying the person from whose body the material has come and is not likely to come into possession of it.
- In these circumstances samples are generally unlinked to any form of identification by using a unique laboratory number.

6.2. Existing holdings

There are no statutory requirements as to the need for consent to the storage or use of tissue from existing holdings for research. This does not mean that existing holdings can be used freely without regard to issues of consent or other ethical considerations; the potential benefits must outweigh any potential harm to donors of the samples. If consent is not available it should be sought if it is practicable.

6.3. DNA

The consent requirements of the Act do not apply to existing holdings.as long as the analysis is for research in connection with disorders or functioning of the human body.

Further information relating to consent and the HT Act can be found in the HT Act's Code of Practice 1 -Consent and Code of Practice 9 - Research.

7. Procedure

7.1. General Principles

- It is a legal requirement to gain the approval of an Approved Research Ethics Committee and from the Institution hosting the Research, through their Research and Development Approval Process. No Research can commence without this.
- Consent must be sought where tissue is taken from the living for research, unless the research is under a current ethically approved project and the material is anonymised. It is recommended that consent is obtained in all cases.
- It is an offence under the HT Act to store relevant material taken after death without consent for any scheduled purpose.
- Human tissue must be stored securely, in line with health and safety guidelines, and appropriate records kept.

- Long-term storage is acceptable where appropriate and if consent has been granted. There must be a register of holdings which is audited annually.
- The DI is responsible for ensuring that records are maintained in the area covered by the licence.
- OCDEM Local Rules for Containment Level 2 Laboratories and OCDEM SOP S1 – 'Laboratory Rules for the Safe Handling of Blood , Body Fluids and other Human Tissues: Containment Level 2' must be adhered to all at times when handling samples.

7.2. Methods of storage

The integrity of the samples must be maintained at all times; if possible freezers and liquid nitrogen vessels used for the storage of relevant material should be on a dial out alarm system. For storage facilities where no dial out alarm is available there must be a robust protocol for checking them at weekends or during holiday periods.

7.2.1. Tissue should be stored in line with current good practice on:

- Security.
- Traceability, including information about risk. Records should detail the location of the materials.
- Health and safety, including appropriate containment levels for the storage, transportation and handling of materials that may pose a risk to others.

7.2.2. Guidelines to be observed for the storing of Human Tissue:

- Human Tissue must be stored using recognised methods as per standard practice and guidance and labelled accordingly.
- The appropriate label must be anonymised.
- Human tissue must be stored in an area that must be secured at all times.

7.3. Appropriate storage period

- There is currently no time limit on the storage of organs and tissue, averting the potential for the premature loss of useful material. Long-term storage in tissue banks for future research may be acceptable to many donors or their relatives who have given consent for such storage.
- Holdings must be updated on an annual basis.
- There should be a formal annual audit of holdings.

8. Sample Logging & Storage

8.1. Samples originating from the CRU in OCDEM

- All studies must be registered with the CRU.
- Each study should have a log file relating to the trial or project. These files should be clearly identified; the spreadsheets must contain the ethics number for the study along with project title or acronym.
- All information about the subjects for each trial must be kept in secure files in an organised way.
- Samples must be transferred to OCDEM laboratories or transported to third parties as soon as possible after collection.

8.2. Receipt in OCDEM Laboratories

- All samples must be issued a unique identifier, be labelled appropriately and logged into a sample database.
- Samples must be logged and stored as appropriate as soon as possible after receipt.
- There must be a database in existence for all relevant material that contains the following information:
  - Source of sample
  - Date of collection
  - Consent, whom taken by, plus any restrictions on consent must be logged
  - Study and ethics number if known
  - Name of the researcher
  - Type of sample
  - Storage location
  - Number of sample aliquots, if relevant
  - Number of aliquots remaining
  - Removal of sample for what purpose
  - Details of third parties if samples transported outside OCDEM
  - Record of Sample Transfer Agreement if applicable
  - Record of when samples are processed
  - Disposal of sample

9. Sample Tracking

- Information on the current location of all relevant material must be logged on the sample database.
- Withdrawing samples from their primary site of storage (e.g. a -80^0 C freezer) should be carried out only by the responsible scientist for the purpose of conducting sample analysis or re-analysis.
- When the responsible scientist removes patient samples for the purpose of analysis, details of the withdrawal should be recorded on the sample database.
- After analysis, if samples are not returned to the freezer but disposed of, or the sample exhausted, then the date of disposal/used up is entered into the relevant column of the database.
- If samples are dispatched to another laboratory, whether within the UK or abroad, this must be recorded.
- If the samples are transferred to a new location (different freezer etc) then this information must also be recorded.
- When the management decision is taken to dispose of samples, the date of their disposal must be recorded.

10.Transport of relevant material

When there is a need to transport relevant material to other departments outside OCDEM, the instructions contained in SOP S7 ‘Transporting Biological Specimens, Category B (non hazardous) on Dry Ice’ must be adhered to. Only those that have been trained are allowed to authorise the transport of materials.

Relevant material that is to be transported to third parties is subject to either: a sample transfer agreement; material transfer agreement (MTA); service level agreement or contract that has been signed by all parties. The document must contain details of whether the

samples will be returned to OCDEM, destroyed or completely used up by the analysis to be performed.

The approved MTA for the University of Oxford can be found at: https://www1.admin.ox.ac.uk/researchsupport/contracts/mta/human/.

The details of the third parties must be completed in the sample database and a copy of the transfer agreement or contract should be available for inspection if required.

11.Sample disposal

See OCDEM SOP I8 ‘Disposal of Human Tissue and Relevant Material (Research)’ for information regarding the disposal of relevant material