The Oxford Centre for Diabetes, Endocrinology and Metabolism

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Freezers used for the storage of Relevant Material in OCDEM

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	Name	Signature	Date
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Update History

Version	Date	Reason for update	Updated/reviewed by :	Date next review due
1	1 Mar 2012	New SOP, accepted by DI and Head of Safety	Author: SMH	Mar 2012
1	1 Mar 2012	Review – no changes	SMH	Mar 2014
1.1	25/03/2014	Change of header, section added about available freezers for relocation	SMH	March 2016
1.2	16/03/2016	HoD changed, available back up freezers updated and maintenance company details	SMH, Approved by DI and HoD	April 2018

Contents

1 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 'Relevant Material' as defined by the HT Act, which freezers are acceptable for storage and what to do if there is a failure in one of the freezers. .

2 Scope

Human tissue samples used in research covered by the Human Tissue Authority (HTA) licence granted to OCDEM, are required to be stored under conditions that do not threaten their integrity, particularly that of thawing.
This SOP applies to all University of Oxford staff, students and visitors within OCDEM responsible for the storage of relevant material.

3 Definitions

3.1 Designated Individual and Persons Designated

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

3.2 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 'HTA list of materials' can also be found on the OCDEM website on the 'Staff Pages' in the Human Tissue Authority folder.

3.3 Storage

3.3.1 To maintain tissue samples under appropriate controlled conditions.

4 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 Safety Advisory Committee is responsible for ensuring that the SOP remains fit for purpose.

5 Procedure

5.1 General Principles

- Human tissue must be stored securely, in line with health and safety guidelines, and appropriate records kept. See *OCDEM SOP I 9: Sample logging, storage and tracking for the purposes of research* for more information.
- 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.

5.2 Methods of storage

- The integrity of the samples must be maintained at all times; freezers and liquid nitrogen vessels used for the storage of relevant material must be on a dial out alarm system.
- Freezers used for storage of relevant material must be located in one of the OCDEM freezer morgues, and not in the main laboratories.
- Liquid nitrogen vessels are located in a secure room on the ground floor. Access is only allowed to researchers who have been trained in the use of liquid nitrogen.
- All freezers and liquid nitrogen vessels used for the storage of relevant material must be clearly labelled.
- A list of emergency contact numbers must be posted in all laboratories and a copy lodged with the main Churchill Hospital switchboard.

6 Maintenance

All freezers and liquid nitrogen vessels used for the storage of relevant material must be subject to a maintenance contract. The following companies provide service and maintenance:
McAlpine Grant Ilco (MGI), based in Osney Mead in Oxford. Their phone number is: 01865 251225.
LAB_3 VWR Technical services; telephone 01179 515696 or email lab3service@uk.vwr.com.
Panasonic biomedical service and maintenance can be found via their website: http://www.biomedical.panasonic.co.uk/service-downloads/request-a-service The service reports should be kept within each Group.

7 Alarms

All the alarms in OCDEM work on a system that either sends out an SMS text to the persons programmed into the alarm system or links to the hospital switchboard who keep a record of staff telephone numbers for call out. If the nominated persons are not available to deal with the alarm they must delegate the responsibility to another responsible person; the nominated person can either change the telephone number in the alarm system or telephone them immediately after receipt of the text message.

8 Freezer failures

Freezer failures must be monitored; the alarms sent by text message notify the temperature of the freezer at the time the text was sent. On a working day these must be investigated immediately. During the evening, night time, weekend or holiday period the freezer temperature can be monitored via the text messages. If the temperature drops by 20°C (which in most cases will take about six hours) the alarm must be investigated.

8.1 Power failure

Follow the instructions in *OCDEM SOP I4: Power Failures and Freezers within OCDEM*.

8.2 Freezer failure during the working day

- Call in MGI to investigate the cause of the failure and monitor the freezer temperature.
- If the engineer's visit does not have a short lead time and/or the temperature falls by more than 20°C relocate the sample to another freezer or freezers.

8.3 Freezer failure outside the working day

- Monitor the freezer temperature via the text messages.
- If the temperature drops by 20°C a visit to the department will be required.
- Relocated the samples to another freezer or freezers.
- Call in MGI to investigate the cause.

9 Logging the location

When samples are moved to another freezer or freezers the location must be logged to ensure they are all accounted for.
When samples are returned to the repaired or replaced freezer an audit will be required to ensure the samples have all been returned. Records must be kept of this audit.

10 Available freezers for relocation

Within freezer morgue F17 there are -80°C freezers available for use in the event of a freezer failure. The large chest freezer is empty except for a supply of dry ice; the dry ice can be used to keep samples frozen during relocation and any excess stored in the short term dry ice storage container located in laboratory F12, freeing up this freezer for use. There are also three empty -80°C upright freezers kept running in F17 available for use during a freezer failure.

11 Reporting the Failure

The DI and the PD(s) must be made aware of all freezer failures. All freezer failures must be reported on an Adverse Event/Incident form in line with the instructions contained in OCDEM SOP I10 Adverse Events and Incident Reporting relating to Human Tissue for Research. Both of these documents can be found on the 'Staff Pages' of the OCDEM website in the 'Human Tissue Authority' folder.