The Oxford Centre for Diabetes, Endocrinology and Metabolism

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Governance Arrangements for the Administration of the Human Tissue Act in OCDEM

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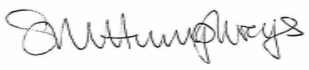
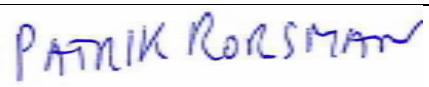
Author	Sandy Humphreys		05/10/2015
Approved by DI			05/10/2015
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Update History

Version	Date	Reason for update	Updated/reviewed by :	Date next review due
1	6/2/2012	New SOP	Author: SMH, approved by DI.	February 2014
2.0	10/09/2012	Reduction of content – now a supplementary document to Quality Manual	SMH, approved by DI	September 2013
2.0	03/09/2013	No changes	SMH	September 2014
2.1	23/09/2014	Department Header changed, no other changes	SMH	September 2015
2.2	05/10/2015	Change of Head of Department and links updated. No other changes	SMH, approved by DI	October 2016

Contents

1. Purpose

The purpose of this SOP is to describe the arrangements in place to ensure appropriate governance of the Human Tissue Authority (HTA) Licensed Premises at OCDEM. It is supplementary to the *Quality Manual for the Administration of the Human Tissue Act in OCDEM* and must be read in conjunction with the Quality Manual.

2. Scope

The scope of this SOP is to describe the channels of communication and hierarchy of responsibilities in place at OCDEM to facilitate the administration of the HTA Licence. It covers the governance structure and the reporting lines of members of the Department.

3. Definitions

3.1. A *User* is any person based in OCDEM Laboratories working on relevant material.

3.2. A *person responsible for storage or disposal* is any person within OCDEM who is responsible for the physical storage or disposal of relevant material and/or the updating of information into the relevant database.

4. Responsibilities

4.1. Users and those responsible for storage and disposal

It is the responsibility of all staff to ensure that:

- They adhere to the procedure outlined in *the Quality Manual for the Administration of the Human Tissue Act in OCDEM* and this governance SOP.
- They inform the Designated Individual (DI) or one of the Persons Designated (PD) of any problems regarding the governance of this licence.

5. Governance Structure

There is no formal Governance Group within OCDEM due to the small size of the Department; the HT Act is a standing item on the agenda of the OCDEM Safety advisory Committee meetings and the Laboratory Managers' Group meetings; all items relating to the HTA are reported to these meetings and to the OCDEM Management Board if appropriate. The OCDEM Safety Advisory Committee and Laboratory Managers meet once a term and the OCDEM Management Board meets monthly.

5.1. Membership OCDEM Committees

The membership of the OCDEM Safety Advisory Committee; Lab Managers Group and OCDEM Management Board can be found on the 'Staff Pages' of the OCDEM website in the 'OCDEM Department Committees' folder. Members of the OCDEM Safety Advisory Committee and Lab Managers Group are all University of Oxford staff or students. The OCDEM Management Board consists of members from both the University of Oxford and the Oxford University Hospitals NHS Foundation Trust staff.

5.1.1. Terms of Reference for OCDEM Safety Advisory Committee

The Committee's terms of reference are to adopt all reasonable practicable measures:

- To secure the health, safety and welfare of all employees at places of work under OCDEM's control, and provide safety advice to members of staff.
- To protect students and other persons who are lawfully on OCDEM's premises against risk to their health or safety, which might arise out of activities in those places.
- To maintain machinery and equipment and ensure OCDEM is a safe and healthy place to work.
- Implement the University's safety policies and guide lines; keeping up to date with safety developments.
- Investigate and resolve any safety issues.
- A forum for matters relating to HTA licensed procedures within OCDEM.

5.1.2. Terms of Reference for the OCDEM Laboratory Managers' meetings

The Lab Managers terms of reference are to ensure the efficient and safe running of the laboratories and the staff/students working within them; and to make sure all OCDEM and University Rules and UK Legislation are adhered to.

- To review Health and Safety.
- To review laboratory accidents and incidents.
- To review laboratory practices and procedures.
- Purchasing, maintenance and sharing of equipment and resources.
- The Laboratory Managers Group shall have no executive authority, but may make representations to the OCDEM Management Board in writing.

5.1.3. OCDEM Management Board Terms of Reference

The Management Board is responsible for:

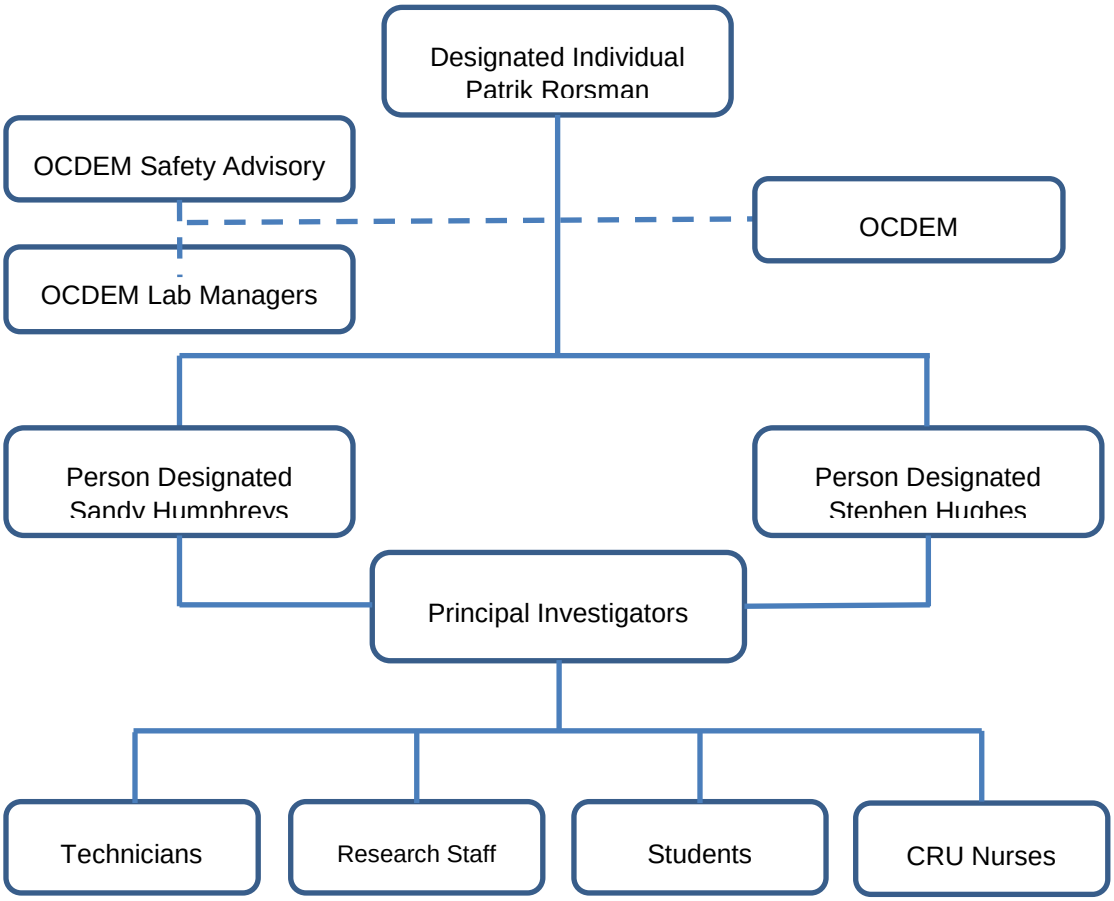
- Developing OCDEM's strategic vision (both domestic and international)
- Receiving and considering reports on matters related to the scientific organisation of the Department and adherence to health and safety regulations
- Considering and approving recommendations on core resource and space allocation in the Department
- Developing and implementing senior appointment recruitment
- Developing and implementing principles of good practice in the Department in accordance with the University and NHS policies and procedures
- Receiving and considering reports from the OCDEM Statutory Groups:
  Safety Committee
  GM Committee
  Radiation Committee
- Receiving and considering reports from the OCDEM non statutory groups
  Clinical Research Unit User Group
  Graduate Studies

Patient Participation Forum
Senior Academic Faculty
Clinical Unit Meeting
Islet Cell Isolation/Transplantation
Lab Managers
BRC Diabetes Theme Meeting
RDM Management Board
Athena Swan Assessement Team
Space Committee

5.2. Lines of Communication

The organogram in Figure 1 shows the lines of communication between those working with human tissue, those responsible for the storage and disposal of human tissue and those responsible for compliance with the Human Tissue Act (HT Act).

Figure 1: OCDEM Organisation Responsibility Chart



6. Standard Operating Procedures

6.1. Core SOPs

The DI is responsible for ensuring core Standard Operating Procedures (SOPs) are produced; all SOPs will be approved by the DI and accepted by the OCDEM Safety Advisory Committee. SOPs will be reviewed at no more than two yearly intervals. These SOPs will be stored on the OCDEM website on the 'Staff Pages' in the 'Human Tissue Authority' folder.

SOPs are available for:

- Adverse events and incidents
- Consent (available from the Nurse Manager in the Clinical Research Unit)
- Control of documents
- Disposal of human tissue and relevant material (Research)
- Guidance on writing an SOP
- Governance Arrangements
- Quality Manual
- Sample logging, storage, and tracking for the purposes of research
- Transport of samples

A full list of available core SOPs is in Appendix 2 of the Quality Manual.

6.2. Group SOPs

All Groups must have SOPs for HTA related activities. These must be updated when procedural changes occur, including the introduction of new equipment. Group SOPs will be reviewed at no more than three yearly intervals.

7. Induction of New Staff

At induction all new staff who will be using relevant material in their work will be expected to review the pages on the OCDEM web site to familiarise themselves with the policies in place and to attend a formal training session with their supervisor.

8. Sample Tracking

All Principal Investigators and staff using Relevant Material must be able to demonstrate the audit trail of a sample when required to do so. The DI and PDs will expect staff to be able to track a sample from the consent form to disposal.