The Oxford Centre for Diabetes, Endocrinology and Metabolism

Radcliffe Department of Medicine

OCDEM, Churchill Hospital, Oxford OX3 7LE

Head of Department: Prof Fredrik Karpe
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Stephen Hughes (Islet Lab)

Adverse Event and Incident Reporting relating to Human Tissue for Research

SOP Number:	OCDEM I 10
Version	1.1
Supercedes:	1.0
Effective date	20/07/2015
Review Date	July 2017

	Name	**Signature**	**Date**
Author	Sandy Humphreys		04/07/2015
Approved by DI	Patrik Rorsman		15/07/2015
Accepted by OCDEM SAC	Fredrik Karpe		20/07/2015

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Update History

Version	Date	Reason for update	Updated/reviewed by :	Date next review due
1	1/5/2011	New SOP	Author: SMH, approved by DI.	May 2013
1	13/05/2013	No changes	SMH	May 2015
1.1	14/07/2016	Changes to Header and HoD, updated links.	SMH	July 2017

Contents

1 Purpose

The purpose of this SOP is to describe the process of identifying, reporting and acting upon Adverse Events and Incidents (AE/I) associated with the acquisition, storage, use and disposal of human tissues for research purposes.

2 Scope

The scope of this SOP is to define an AE/I in relation to human tissue research. It details the reporting mechanism for an AE/I and the responsibilities of the User, the Human Tissue Authority (HTA) Designated Individual (DI), Persons Designated (PD), and the OCDEM Safety Advisory Committee (SAC).
This policy must be used in conjunction with University of Oxford accident and incident reporting policies as well as other applicable University policies (see 5.2.1).

3 Definitions

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

3.2 An *adverse event* is any event that:

- Caused harm or had the potential to cause harm to staff or visitors on OCDEM HTA licensed premises due to the incorrect procurement or processing of relevant material;
- led to or had the potential to lead to a breach of security in the laboratories in which human tissue is stored;
- caused harm or had the potential to cause harm to stored human tissue (including loss);
- gave rise to an internal inquiry in relation to the misuse of relevant material.

3.3 An *incident* can be considered as an untoward event or sequence of events:

- That has caused or has the potential to cause damage, harm, or loss to relevant material or the facility the tissue is stored in;
- where an important policy, procedure, or practice was not followed by staff leading to detriment or the potential detriment of the relevant material or storage facilities.

4 Reporting and Timescales

4.1 Any AE/I that occurs under the conditions of a HTA licence must be reported and recorded. If the AE falls into the Catastrophic grading all efforts must be made to contact the DI or one of the PDs immediately, either by telephone or email. All AE/I with a lower grading must be reported within 24 hours.

4.2 AE/I must be reported by completing an ‘OCDEM Adverse Event/Incident Report Form’ (see Appendix 1); the form can be found on the ‘Staff Pages’ of the OCDEM intranet in the ‘OCDEM Local Rules and SOPs’ section.

4.3 All AE/I Report Forms must be forwarded to the PD for OCDEM within 24 hours of the AE/I; if the PD for OCDEM is not available the report would be given to the PD for the Islet lab. In the absence of both PDs the report must be made to the DI. The PDs will inform the DI of all AE/I.

4.4 The PD/DI who received the report must discuss the AE/I with the affected Group / person to decide on any immediate remedial or corrective action and to confirm the grading within 24 hours of receiving the report.

4.5 All reasonable enquiries or investigations relevant to the AE/I must have been made within two weeks of the AE/I; the investigation will be carried out by the Laboratory Manager of the Group affected.

4.6 Feedback from the enquiry must be disseminated to staff by the PD/DI who received the report within one week of the enquiry being completed.

4.7 As OCDEM is a small department there is no formal HTA Governance Committee and matters relating to HTA activities are reported to and discussed at the OCDEM SAC.

4.8 A full report/update of the AE/I, action taken and further planned activities must be submitted by the PD/DI who has dealt with the matter, to the Chair of the OCDEM SAC for presentation at the next scheduled meeting, The Chair of OCDEM SAC will report to the OCDEM Management Board if the AE/I is classed above Moderate.

4.9 All reports to be filed in the appropriate 'Adverse Events/ Incidents' folder located on the Safety Station in laboratory F40, there are two files: 'In progress' and 'Completed'. The 'Adverse Event and Incident log' must be completed throughout the investigation by the PD/DI who received the report. This log can be found at 'Shared\HTA Documents\logs\SOP I10 Record Log.xlsx'.

5 Responsibilities

5.1 User

It is the responsibility of the user to ensure that:

5.1.1 They adhere to the AE/I reporting procedure outlined in this SOP.

5.1.2 They report any AE/I to the PD/DI for OCDEM as outlined in section 4.

5.2 Person Designated / Designated Individual

It is the responsibility of the PD/DI to ensure that:

5.2.1 An AE/ I form (see Appendix 1) has been completed by the user and reviewed for accuracy. Depending on the nature of the AE/I an accident report form may need to be completed for the University of Oxford Safety Office; the University policy for reporting accidents and incidents can be found at: http://www.admin.ox.ac.uk/safety/policy-statements/upss114/.

5.2.2 A discussion is held with the affected Group/person to decide on any immediate remedial or corrective action and to confirm the grading

5.2.3 All reasonable enquiries or investigations relevant to the AE/I have been made and information disseminated to staff.

5.2.4 Information about an AE/I is reported to the OCDEM Head of Safety (Chair of the OCDEM SAC) as soon as is reasonably practicable.

5.2.5 An AE/I is followed up until completion of all remedial actions by the Group Laboratory Manager and the report is closed; this should not extend beyond two months of the AE/I.

5.2.6 OCDEM AE/I trends are monitored by the Laboratory Managers and discussed at their termly meetings to ensure appropriate action is taken to address system failures.

5.3 OCDEM Safety Advisory Committee

It is the responsibility of the OCDEM SAC to ensure that:

5.3.1 An appropriate AE/I reporting procedure is in place and is reviewed every two years.

5.3.2 All AE/I are followed up until completion; this will be a permanent item on the OCDEM SAC meeting agenda.

6 Investigating Adverse Events and Incidents

6.1 All AE/I must be followed-up until closure.

6.2 The DI /PD who received the initial report is responsible for carrying out an immediate local investigation which should be communicated to the Chair of the OCDEM SAC for discussion at the next OCDEM SAC meeting, and, if more than Moderate grading, to the OCDEM Management Board.

6.3 Depending on the severity of the AE/I, there will be a number of actions which need to be taken in the subsequent hours and days after an AE/I:

- The DI /PD who received the initial report will organise a meeting/discussion with the Group Laboratory Manager.
- An investigation into what happened, why did it happen, how did it happen will be carried out; decisions will be made about what can be done to prevent or reduce the chance of it happening again. A review of risk assessment will be encouraged.
- If the AE/I is likely to result in immediate media interest, a delegated person will contact appropriate personnel at the University of Oxford Press Office; the delegated person will be appointed by the DI.
- The outcome of any AE/I of grading above Moderate will be reported to the OCDEM Management Board.

7 Grading of Adverse Events/ Incidents associated with OCDEM HTA Licensable Activities

5	Catastrophic	Caused harm or had the potential to cause harm to staff or visitors due to the incorrect procurement or processing of relevant material. Caused harm or had the potential to cause harm to stored human tissue. Loss of unique relevant material. Loss of participant identification records in public area or during transportation.
4	Major	Relevant material removed from a participant, stored or used without appropriate consent. Staff member seeking consent who has not been appropriately trained. Relevant material used for a research study which has not been approved by NHS REC. Breach of Data protection/confidentiality involving relevant material. Specimen acquired from wrong participant or specimen incorrectly labelled. Freezer/ Nitrogen back-up and alarm failure resulting in destruction of material. Unauthorised access to storage facility. Relevant material placed with non-clinical or animal waste for disposal. Relevant material lost or quality compromised during transportation.
3	Moderate	Relevant material transported to or from OCDEM without appropriate contract/ MTA in place. Not using appropriate tracking system to record material acquisition, storage, use and disposal. Inappropriate transport of specimens. Incorrect type of specimen acquired. Power failure with no adverse effects**.**
2	Minor	Labelling error that can be accurately rectified. Incorrect version of policy or SOP in use.
1	Insignificant	Incident occurred which resulted in no compromise of relevant material.
0	Near Miss	AE/ I could have happened if intervention had not been made.

Appendix 1

The Oxford Centre for Diabetes, Endocrinology and Metabolism

OCDEM, Churchill Hospital, Oxford OX3 7LE

Radcliffe Department of Medicine

UNIVERSITY OF OXFORD

OCDEM Adverse Event/ Incident Report Form

The completed form must be submitted to the OCDEM Designated Individual or Person Designated within 24 hours of being made aware of an adverse event/incident under the OCDEM HTA licence. Please provide as much relevant information as possible. Please ensure that other relevant University of Oxford accident/incident report forms are completed.

1. HTA Licence details

HTA Premises	HTA licence number
Oxford Centre for Diabetes, Endocrinology and Metabolism, Churchill Hospital, Oxford, OX3 7LE	12326
Designated individual and contact number:	Email address:
Prof Patrik Rorsman 01865 857348	patrik.rorsman@ocdem.ox.ac.uk
Person(s) Designated and contact number:	Email address
Sandy Humphreys, 01865 857216 Stephen Hughes, 01865 857507	sandy.humphreys@ocdem.ox.ac.uk stephen.hughes@nds.ox.ac.uk

2. Reporting

Report Number (To be assigned by PD / DI)		
Adverse Event/Incident reported to:	**By:**	**Date**
DI (Patrik Rorsman) PD (Sandy Humphreys) PD (Stephen Hughes) (Delete as appropriate)		
Head of Safety		
OCDEM Safety Advisory Committee		
OCDEM Management Board (If required)		

3. Adverse Event/Incident

Date Adverse Event/Incident occurred
Date DI or PD informed of/made aware of Adverse Event/Incident
Room number of Adverse Event/Incident
Summary of Adverse Event/Incident
Grade of Adverse event/incident, see section 7 of SOP I 10: Adverse Event and Incident Reporting relating to Human Tissue for Research for examples of grading.

4. Initial action taken by DI/PD since being made aware of Adverse Event or Incident

Initial action taken:
Corrective
Preventative
Date of resolution, if applicable

5. Any other relevant information

Please provide any additional information relevant to the Adverse Event/Incident

Report completed by:	Date report submitted:

6. Follow Up Actions

Follow Up Action:	Assigned to:	Target Date:	Completion Date

DI or PD to confirm all actions are complete and report can be closed

Report Closed:	Signature:	Name

A copy of the report should be filed by the User; the original to be filed in the 'Adverse Event/Incident' folder located on the Safety Station in Laboratory F40.