The Oxford Centre for Diabetes, Endocrinology and Metabolism
Nuffield Department of Clinical Medicine, University of Oxford

OCDEM, Churchill Hospital, Oxford OX3 7LE

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	**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:**	**On:** (dd/mm/yyyy)
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.