

Site visit inspection report on compliance with HTA minimum standards

OCDEM Oxford Centre for Diabetes, Endocrinology and Metabolism

HTA licensing number 12326

Licensed under the Human Tissue Act 2004 for the

- **storage of relevant material which has come from a human body for use for a scheduled purpose**

12 April 2012

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

OCDEM Oxford Centre for Diabetes, Endocrinology and Metabolism (the establishment) was found to meet all HTA standards. Advice is given in this report on how to strengthen quality management systems at departmental and local level.

Examples of strengths are included in the concluding comments section of this report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual (DI), Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set out in Paragraph 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

Nine Principal Investigators (PIs) at this establishment carry out research into diabetes and lipid metabolism disorders. Six of these PIs store samples of relevant material (including whole blood and urine samples, biopsy tissue, wax blocks and slides) and non-relevant material (DNA, serum and plasma) for use in research. Depending on the tissue type, samples may be stored in -80°C freezers, liquid nitrogen tanks, fridges, walk-in coldrooms or at ambient temperature. The majority of projects at the establishment have NHS Research Ethics Committee (REC) approval. Tissue collection for many projects is ongoing, though for a small number of projects, tissue donation ceased some years ago. Tissue is donated by healthy adult volunteers and by surgical patients. Volunteer donors who enrol on the research recruitment register give blood or urine samples at the establishment's Clinical Research Unit (CRU).

The establishment has been licensed by the HTA since September 2007. This report describes its first routine site visit inspection in April 2012. The inspectors met with PIs and research staff, reviewed documentation, and visually inspected tissue storage facilities. Traceability audits were carried out in five laboratories. While all samples were traceable from consent through to storage, the inspectors did note transcription errors in some records, and deficiencies in recording the numbers and locations of microscope slides cut from wax blocks (advice items 1, 5).

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ1	<p>The departmental standard operating procedure (SOP) 'Governance arrangements for the administration of the Human Tissue Act in OCDEM' is, in essence, a quality manual. The DI is advised to ensure that all researchers are aware of this document, in order to promote a more consistent approach to quality management across the establishment. The DI is also advised to expand the scope of this document to include, for example:</p> <ul style="list-style-type: none">• reference to the HTA Codes of practice on Consent, Disposal and Research;• relevant university policies on such areas as information management and data protection;• terms of reference, and schedule, for key meetings such as the Laboratory Managers meeting.
2.	GQ1	<p>The DI is advised to develop a policy to cover what will happen to a PI's tissue samples, and records of traceability, when that person retires from the establishment.</p>
3.	GQ2	<p>There is an inconsistent approach to carrying out audits within individual research groups. The DI is advised to remind researchers of the guidance on audits in the departmental 'Governance arrangements for the administration of the Human Tissue Act in OCDEM' SOP, and in particular:</p> <ul style="list-style-type: none">• how regularly audits should be carried out;• the range of audits which could be conducted (e.g. traceability audits of electronic / paper records and stored tissue, process audits);• how to record the findings of audits, including any non-conformances, which should be managed in line with the departmental SOP I10 on management of adverse incidents.
4.	GQ4	<p>The DI is advised to consider the storage arrangements for key records, such as laboratory samples books, and when it is appropriate to move those to more secure archive facilities.</p>
5.	GQ4, D2	<p>The DI is advised that numbers of slides prepared from wax-embedded or snap-frozen tissue, their storage locations and (where applicable) their disposal should be recorded. As per advice item 3, slides should be included in traceability audits.</p>

6.	GQ5	The DI is advised that a formal agreement, for example as part of a material transfer agreement, should be in place whenever samples are transferred to and from another establishment, irrespective of whether such samples are relevant or non-relevant material under the Human Tissue Act 2004.
7.	GQ8	<p>The DI is advised to expand the departmental risk assessment on risks associated with storage and use of human tissue (RA14) to include possible risks associated with;</p> <ul style="list-style-type: none"> • traceability; • samples being used for research without the appropriate consent; • freezer temperatures not being routinely logged.

Concluding comments

Procedures for seeking donor consent, and the establishment's premises and facilities, are suitable. Quality management at a departmental level is satisfactory, with a good range of departmental SOPs and risk assessments, although there is some variation between laboratories in terms of local SOPs and audits. A detailed quality manual could foster a more coherent approach across all research groups.

Examples of strengths noted at the inspection include;

- the clear and concise information leaflet for donors who may wish to join the research recruitment register;
- the thorough training in seeking consent which CRU research nurses receive, and;
- the induction arrangements for new staff and students at the establishment.

The HTA has assessed the establishment as suitable to be licensed for the specified activity.

Report sent to DI for factual accuracy: 25 April 2012

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 11 May 2012

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
<ul style="list-style-type: none">• Consent forms comply with the HTA's Code of Practice• Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose• If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice• Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice• Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
<ul style="list-style-type: none">• Standard operating procedures (SOPs) detail the procedure for providing information on consent• Agreements with third parties contain appropriate information• Independent interpreters are available when appropriate• Information is available in suitable formats, appropriate to the situation• Consent procedures have been ethically approved
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
<ul style="list-style-type: none">• Standard operating procedures (SOPs) detail the consent process• Evidence of suitable training of staff involved in seeking consent• Records demonstrate up-to-date staff training• Competency is assessed and maintained
Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
<ul style="list-style-type: none">• Policies and procedures in place are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body• Appropriate risk management systems are in place• Regular governance meetings are held; for example, health and safety and risk management

<p>committees, agendas and minutes</p> <ul style="list-style-type: none"> • Complaints system
GQ2 There is a documented system of quality management and audit
<ul style="list-style-type: none"> • A document control system, covering all documented policies and standard operating procedures (SOPs). • Schedule of audits • Change control mechanisms for the implementation of new operational procedures
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
<ul style="list-style-type: none"> • Qualifications of staff and training are recorded, records showing attendance at training • Orientation and induction programmes • Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training • Training and reference manuals • Staff appraisal / review records and personal development plans are in place
GQ4 There is a systematic and planned approach to the management of records
<ul style="list-style-type: none"> • Documented procedures for the creation, amendment, retention and destruction of records • Regular audit of record content to check for completeness, legibility and accuracy • Back-up / recovery facility in the event of loss of records • Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)
GQ5 There are documented procedures for distribution of body parts, tissues or cells
<ul style="list-style-type: none"> • A process is in place to review the release of relevant material to other organisations • An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail
<ul style="list-style-type: none"> • There is an identification system which assigns a unique code to each donation and to each of the products associated with it • An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

GQ7 There are systems to ensure that all adverse events are investigated promptly
<ul style="list-style-type: none"> • Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
<ul style="list-style-type: none"> • Documented risk assessments for all practices and processes • Risk assessments are reviewed when appropriate • Staff can access risk assessments and are made aware of local hazards at training
Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
<ul style="list-style-type: none"> • A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
<ul style="list-style-type: none"> • Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • Appropriate health and safety controls are in place
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
<ul style="list-style-type: none"> • Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Contingency plans are in place in case of failure in storage area • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis • Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation
- A system is in place to ensure that traceability of relevant material is maintained during transport
- Records of transportation and delivery
- Records are kept of any agreements with recipients of relevant material
- Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Records of calibration, validation and maintenance, including any agreements with maintenance companies
- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- Documented disposal policy
- Policy is made available to the public
- Compliance with health and safety recommendations

D2 The reason for disposal and the methods used are carefully documented

- Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal
- Where applicable, disposal arrangements reflect specified wishes

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

or

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

- (1) A notice of proposal being issued to revoke the licence
- (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- (3) A notice of suspension of licensable activities
- (4) Additional conditions being proposed
- (5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.