Site visit inspection report on compliance with HTA minimum standards

Oxford Centre for Diabetes, Endocrinology & 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**

6 October 2016

Summary of inspection findings

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

Although the Oxford Centre for Diabetes, Endocrinology & Metabolism (OCDEM) were found to have met most of the HTA's licensing standards, a minor shortfall was identified against standard GQ2. This was in relation to audits against HTA standards and tissue in storage.

The establishment was provided with advice about areas that could be improved further. Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

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

The statutory duties of the Designated Individual are set down in Section 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 licenses 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

The Oxford Centre for Diabetes, Endocrinology and Metabolism (OCDEM) is a centre which combines clinical care, research and education in diabetes, endocrine and metabolic diseases. It aims to enhance understanding of these diseases and to accelerate the search for new treatments and cures. OCDEM is based on the Churchill Hospital site in Oxfordshire.

OCDEM stores over 1.5 million samples of tissues and cells. The majority are stored for projects which have received ethical approval from recognised Research Ethics Committees (RECs) but some existing holdings, and tissue for projects where ethical approval from recognised RECs has ended, are stored under the HTA storage licence.

Tissue and cells for research are donated mainly by healthy volunteers for specific studies. Consent for each study is sought by trained nurses at the Clinical Research Unit (CRU), where clear information about the study and what will happen is given to the donor before consent is sought. The samples themselves are often obtained at the CRU, which has a number of well-equipped patient bays that are suitable for the purpose.

Research samples are stored in -80°C freezers (gluteal and abdominal adipose tissue, whole blood, serum, plasma and urine) in two different areas in the building, and in liquid nitrogen storage (adipose tissue, muscle, liver and pancreatic tissue biopsies). The freezers are alarmed, with a call out system, which is regularly tested. The temperature monitoring

systems allow temperature trends to be monitored; however, this is not happening in all departments (see Advice, item 6). The freezers display clear signs that contain details of who to contact if there are any problems and highlight that they are for human tissue storage only. There are three, back-up -80°C freezers and a chest freezer, as well as additional storage space in other liquid nitrogen tanks.

The CRU has two - 20°C freezers, in which samples are stored short term before being transferred to permanent storage. The temperature is monitored daily during the working week (Monday to Friday). There are also temperature data loggers, which are checked by laboratory staff each Monday morning to identify if there have been any temperature deviations over the weekend. However, in general, all samples added to the freezers during the working week are moved to their permanent storage area by the corresponding Friday afternoon.

There are two main laboratories where human tissue is stored under the Human Tissue Act 2004. For historical reasons, these departments have two different tracking systems for tissue management - both use barcoded systems and are fit-for-purpose. There are noticeable differences between the two laboratories; the freezers in the Diabetes Research laboratory are not connected to the emergency generator while the freezers in the Oxlip freezer room are and there were inconsistencies in audit and temperature monitoring.

As part of the inspection, an audit of tissue samples was undertaken; this included samples in liquid nitrogen storage and those from -80°C freezers in both storage areas. These were compared with the locations recorded on the different sample tracking systems and with the consent given by the donor. Records where volunteers had withdrawn consent were tracked through the system and reverse audits were also undertaken from the tracking systems to the freezers. A minor discrepancy was found, whereby the location of the sample in the -80°C freezer did not match the record of the location held in the lab (See Advice item 5).

This was the second routine inspection of OCDEM. In addition to traceability audits, the inspection included a visual inspection, interviews with key staff and a document review.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit	There are inconsistencies in audits between departments and an overall lack of audit against HTA standards. The quality manual mentions audits, but gives no clear guidance on what audits should take place or their frequency. Nor does it give any information about how any discrepancies should be followed up to ensure lessons learned are shared across the organisation.	**Minor**

	Where audits do take place they are not done as frequently as the audit schedule indicates with audits against consent from donors only taking place every 18 months to two years. See Advice, items 2 and 3	

Advice

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

No.	Standard	Advice
1.	N/A	The DI should consider appointing a Person Designated for each area where tissue is stored, to support a consistency of approach.
2.	GQ2	There are regular audits in some areas of the establishment but not in all areas. The DI is advised to ensure that audits are undertaken across the facility on a regular basis, following an audit schedule.
3.	GQ2	To reduce the burden on individual departments, the DI should consider using other groups within the organisation to perform cross-departmental audits on each other. This should also help consistency in approach and follow-up of issues identified.
4.	GQ3	Not all training records have been correctly completed. The DI is advised to add a review of training records and competency assessment to the audit schedule.
5.	GQ6	There were some difficulties finding a number of the samples selected on audit on the tracking systems; whilst eventually found the DI should review these systems and develop Standard Operating Procedures for the different systems to ensure ease of traceability for all samples.
6.	PFE3	The continuous temperature monitoring system is not routinely checked in some storage areas. The DI is advised to implement a system whereby the temperatures are reviewed regularly, in all departments, to ensure the freezers and liquid nitrogen tanks are operating as required.
7.	PFE3	The DI should consider linking all freezers containing human tissue to the main emergency generator system.

Concluding comments

A number of areas of good practice were seen during the inspection. Staff had followed the majority of advice and guidance given in the last HTA inspection. There is a commendable approach to consent-seeking, initial consent is taken from volunteers for their contact details to be held on the database and confirmation is sought every two years that they agree for their details to still remain on the database. When a new study requires samples, the donors are contacted again to check whether they consent for their samples to be used in that particular study.

There are some areas of practice that require improvement, including one minor shortfall

against GQ2. The HTA has given advice to the Designated Individual in a number of areas, to make further improvements.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 3 November 2016

Report returned from DI: 15 November 2016

Final report issued: 29 November 2016

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 24 March 2017

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
• 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

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
• Policies and procedures 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 committees, agendas and minutes • Complaints system
GQ2 There is a documented system of quality management and audit
• 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
• 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
• 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
• 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
• 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
• 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
• 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
• 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
• 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.
• 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.