Site visit inspection report on compliance with HTA minimum standards

Peninsula College of Medicine and Dentistry, Exeter

HTA licensing number 12104

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 December 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.

Although the HTA found that Peninsula College of Medicine and Dentistry, Exeter (the establishment) had met the majority of the HTA standards, a minor shortfall was found in relation to consent. Advice has also been provided to the Designated Individual with regard to consent documentation, governance and quality processes, the freezer alarm system and disposal procedures.

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 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

Peninsula College of Medicine and Dentistry carries out research involving the use of human tissue. The majority of the projects have been approved by recognised research ethics committees and are therefore exempt from the licensing requirements of the Human Tissue Act, 2004; however frozen muscle and saliva samples held in the Department of Sport and Health Science are covered only by ethical approval from the University and are therefore stored for use in research under the HTA licence. The majority of these samples were from donors who had been consented by trained staff at the establishment, but a group of the samples had been imported from abroad and there was a lack of information regarding the consent obtained for these (refer to minor shortfall against C1).

This was the first routine inspection of the establishment. The inspection comprised interviews with members of staff, a review of relevant documentation and visual inspection of the freezer storage area. An audit was carried out on five samples stored in the freezer against their storage location on the electronic database. No anomalies were found. Consent records for these samples were also reviewed for all but two of the samples which had been received from abroad. Some variability was noted in the other three consent forms in terms of how fully they had been completed, and advice has been provided against standards C1/2 in this regard.

To date none of these tissue samples have been disposed of by the establishment but records are being kept of samples that have been sent abroad for analysis.

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

Consent

Standard	Inspection findings	Level of shortfall
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.	A set of muscle samples has been received from abroad for which the establishment do not have any details regarding the consent that was obtained for use of these samples. As a result, the establishment were unable to demonstrate that the samples were being used in line with the consent that was given and that any legal requirements of the originating country regarding consent were being met. The establishment has a policy to agree a material transfer agreement before the transport or receipt of samples, which in part confirms that appropriate consent is in place; no such agreement was in place for these samples.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1, C2	Staff at the establishment have audited consent forms and information leaflets and identified variability in how the forms have been completed. For example, the version number of the information leaflet and the witness signature section are not always completed and only some forms have boxes to initial to confirm agreement with specific elements of the consent form. The DI is encouraged to continue with the actions identified to standardise the consent forms used. Furthermore, the DI is advised to consider including the potential use of samples in subsequent research projects, the possibility of sending samples to other establishments or abroad for analysis or other research studies and, if applicable, genetic analysis of the samples. This will allow participants to register their consent or objection to such uses and potentially facilitate the onward use of samples.
2.	GQ2	The establishment has implemented a schedule of audits; however, the DI is advised to ensure traceability audits are also included which track the location of samples in storage, as well as all the documentation that relates to the samples

		selected.
3.	GQ4	Variability in the period of time records are to be kept was noted in donor information leaflets, SOPs and policies. The DI is advised to standardise the period for which records will be kept to make it easier to comply with the requirements of these documents.
4.	GQ7	The DI has recently implemented a system for reporting adverse events which involve human tissue samples. The DI is advised to monitor the reporting of incidents involving all human tissue samples, not just those covered by the licence, so that any trends can be identified and any points of learning shared between all researchers.
5.	GQ8	Risk assessments of health and safety concerns have been carried out which includes the risks associated with the storage of samples. The DI is advised to increase the scope of these risk assessments to include when other risks associated with the loss of integrity or traceability of samples may be present, such as during transportation, as well as the risk of using samples outside the remit of the consent obtained.
6.	PFE3	The freezer where samples are stored is monitored daily and undergoes annual maintenance, which includes the calibration of the temperature probes. The freezer also has an alarm system, but due to the location of this probe and the temperature variation within the freezer, this displays a different temperature (approximately 5 degrees cooler) to that on the freezer itself. The DI is advised to ensure that the alarm set point triggers at the appropriate freezer temperature as determined by the calibrated probe in the freezer.
7.	D1	A disposal policy and SOP are in use which cover the safe disposal of tissue samples; however, the DI is advised to include the bagging of human tissue separately from other clinical waste to ensure sensitive disposal.

Concluding comments

During the inspection a number of areas of good practice were noted, examples of which are given below.

Staff obtaining consent have received an in-house presentation by the Designated Individual on the requirements of the Human Tissue Act, 2004 and completed a commercially available training course on taking consent. This is supported by an SOP detailing the consent process and what information should be provided to ensure the consent given is valid.

The freezers used for storing human tissue have an alarm system to alert staff via mobile phone when the temperature has warmed to a set trigger point. This system also allows staff to check the freezer temperature remotely, which enables checks to be made during weekends and bank holidays. The freezers have CO_2 or generator back-up in case of power failure and a back-up freezer is also available.

There are a few areas of practice that require some improvement, including one minor shortfall. The HTA has given advice to the Designated Individual with respect to standardising consent documents and the timeframe for keeping records; expanding the scope of audits and risk assessments; and ensuring appropriate freezer alarm set points and sensitive disposal processes are in place.

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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 04/01/13

Report returned from DI: 15/01/13

Final report issued: 22/01/13

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: 04 February 2013

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
C2 Information about the consent process is provided and in a variety of formats
• 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
• 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
• 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.