



Site visit inspection report on compliance with HTA minimum standards

Brighton and Sussex Medical School

HTA licensing number 12561

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**

27 July 2016

Summary of inspection findings

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

Brighton and Sussex Medical School (BSMS, the establishment) were found to have met all of the HTA standards.

Advice has been given under the Governance and Quality Systems standards, relating to the labelling and transitioning of tissue under NHS Research Ethics Committee (REC) approval to storage under the HTA licence on the expiry of the REC approval.

Particular examples of 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 (DI), Licence Holder (LH), premises and practices are suitable.

The statutory duties of the DI 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

This report refers to the activities carried out at Brighton and Sussex Medical School. The establishment's HTA licences cover a hub and satellite site, both located at the University of Brighton Campus. At the time of inspection, all tissue was held at the hub site. The current inspection was a routine site visit to assess whether the establishment is continuing to meet the HTA's standards.

The establishment is licensed under the Human Tissue Act 2004 (HT Act) for the storage of relevant material for use for a scheduled purpose. Relevant material obtained from living people is being stored for the scheduled purposes of: obtaining information which may be relevant to another person; research in connection with disorders, or the functioning, of the human body; education or training relating to human health; and quality assurance.

The majority of human tissue currently stored at the establishment is under NHS Research Ethics Committee (REC) approval and therefore is subject to exemption from licensing by the HTA, under the 2006 Regulations; however, the licence is required for a small number of samples where REC approval has run out.

There are also samples held from projects under REC approval where a consortium agreement is in place and samples have been collected by collaborating NHS institutes elsewhere in the UK and sent to BSMS for storage and analysis.

Human tissue sources

Human tissue samples are obtained from NHS patients at the local hospital Trust or healthy adult volunteers (students and staff) within Brighton and Sussex Medical School.

Consent is sought by BSMS or Trust staff, who have received either Good Clinical Practice (GCP) training or consent training provided by School staff. The establishment uses REC-approved consent forms or those approved by the BSMS Ethics Committee and similarly approved participant information sheets. Consent is sought for specific projects and for future ethically approved projects.

Sample storage

Tissue is stored in -80°C freezers or in liquid nitrogen dewars, which are held in an access-controlled area. The freezers are linked to a continuous temperature monitoring unit, which

feeds into a wireless callout system. Temperature excursions outside the set ranges trigger both audible alarms and the callout system and the system is tested regularly. Labels on the freezers indicate whom to contact if any issues are identified. There is a contingency -80°C freezer and there is an agreement in place with security and the fire service to move the freezers themselves in the event of a fire.

There are two liquid nitrogen storage tanks currently in use. These are manually temperature monitored and the liquid nitrogen levels checked five days a week, with additional liquid nitrogen added on Fridays to ensure there is enough to last the weekend.

Tissue is usually moved to a laboratory on an upper floor for research purposes; samples are put on dry ice or in small liquid nitrogen containers for transport.

Traceability

The establishment has recently introduced a new electronic tissue tracking system. Details of all tissue samples stored under the HTA licence have been entered onto this system. From 2015, the details of all new tissue samples going into storage, even if currently under REC approval, are being entered onto this system, so the same traceability system will apply to all human tissue samples. This leaves a gap where tissue taken for older products may fall out of REC approval and do not appear on this system (see advice item 2).

Audits

During the inspection, the HTA carried out seven audits of stored tissue samples. Five samples were selected at random from the dewar containing tissue stored under the HTA licence and these were traced back to electronic records. Two samples were selected from the electronic traceability system and traced back to liquid nitrogen storage. The corresponding consent notifications were also checked; no anomalies were found.

Inspection findings

The HTA found the DI and the CLH to be suitable in accordance with the requirements of the legislation.

Advice

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

No.	Standard	Advice
1.	GQ6	Barcoded labels are used on samples in storage; these labels are not designed for use in liquid nitrogen and can occasionally fall off, compromising traceability. The DI should source labels designed to work in liquid nitrogen, as he intends.
2.	GQ6	All tissue that is subject to licensing under the HT Act is logged on the electronic traceability system, as are all tissues for new REC-approved studies. The DI should ensure that any samples transitioning from storage under REC approval to storage under the HTA licence are also logged on the system.

Concluding comments

The DI has good oversight of activities taking place under the HTA licence. Areas of good

practice include the wide range of risk assessments, which include assessment of risks to stored tissuesamples, audits against HTA standards, and an audit of the disposal company's procedures.

Advice has been given relating to the Governance and Quality Systems standards.

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

Report sent to DI for factual accuracy: 16 August 2016

Report returned from DI: 22 August 2016

Final report issued: 26 August 2016

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below. 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 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

<ul style="list-style-type: none"> • Complaints system
<p>GQ2 There is a documented system of quality management and audit</p>
<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
<p>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills</p>
<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
<p>GQ4 There is a systematic and planned approach to the management of records</p>
<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)
<p>GQ5 There are documented procedures for distribution of body parts, tissues or cells</p>
<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
<p>GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail</p>
<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

- 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 inspection.

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.