Site visit inspection report on compliance with HTA licensing standards

We The Curious

HTA licensing number 12573

Licensed under the Human Tissue Act 2004 for the

Use, for the purpose of public display, of the body of a deceased person, or relevant material which has come from the body of a deceased person.

4 October 2017

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.

We The Curious (the establishment) was found to have met all HTA standards.

The HTA has given advice to the Designated Individual with respect to consent (should any consent for public display be sought in the future), staff training and risk assessments. More general advice regarding the display of the HTA licence has also been given.

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

The establishment has been licensed since October 2010 and this was its second routine site visit inspection to assess whether it is continuing to meet the HTA's standards.

The establishment displays one item of tissue, a human brain, which forms part of an exhibition about the human body which is entitled, 'All about us'. The tissue is suspended in preservation fluid which is contained within a double-skinned display cabinet built specifically for this purpose and which is fixed to the floor to prevent it being knocked over.

Donor consent for the public display of the tissue in the establishment's exhibition was sought by another HTA-licensed establishment which loans the tissue to the museum. The loan of the tissue is covered by an appropriate material transfer agreement and defines each establishment's responsibilities with regards to the tissue.

Description of inspection activities undertaken

The timetable for the site visit was developed in consideration of the establishment's last self-assessed compliance information, as well as pre-inspection discussions with the Designated Individual and review of the previous inspection findings. During the inspection, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

While at the establishment the HTA visited the area where the tissue was being displayed and reviewed the contingency arrangements should the removal of the tissue from display be necessary for any reason. Discussions with establishment staff regarding checking the condition of the tissue, dealing with complaints and enquiries from the public, adverse events and staff training/induction were undertaken during the inspection.

Inspection findings

The HTA found the Licence Holder, the Designated Individual and the premises 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 Designated Individual to consider the following to further improve practices:

No.	Standard	Advice
1.	C2(a)	The establishment, in conjunction with another HTA-licensed establishment, sought appropriate and valid consent for the public display of the tissue in its exhibition. The establishment is advised, should it seek consent from further donors in the future, to consider widening the scope of the consent sought to include possible future uses of the donated tissue. The establishment may wish to consider seeking consent from donors of tissue for use of their tissue in public display in the planned exhibition and in addition, if the donor wishes to consent to further display, display in future exhibitions at the establishment. This may facilitate the establishment in honouring the tissue donor's wishes for longer in displaying the tissue in order to help inform the public's understanding and interest in science.
2.	GQ3(b)	All new staff that will be working on the exhibition floor establishment undergo an induction. As part of this induction, the Designated Individual meets with each member of staff to brief them of the various areas and exhibits within the establishment. During these face to face meetings with new staff, the Designated Individual informs them about the human tissue that is on display, its background including information about the sensitive nature of the exhibit, how to respond to any questions and concerns of the public and what to do in the event of an adverse event. The establishment is advised to document these meetings between the Designated Individual and new staff members as part of the new employee's induction and training records.
3.	GQ6(a)	The establishment is advised to include risks relating to donor consent and the seeking of donor consent to its suite of risk assessments relating to the public display of human tissue. Identifying and assessing possible risks relating to consent and seeking consent may be helpful to the establishment should it seek consent from further tissue donors in the future. Although the establishment has no current plans to expand the collection of human tissue on public display, identifying risks, assessing them and identifying measures to mitigate against these risks may be helpful should the establishment seek consent from more donors in the future.
4.	N/A	The establishment has appropriately displayed its HTA public display licence, in accordance with standard condition 9 (Annex B) of the licence; however, it is not displayed in an area easily accessible to the public. The establishment is advised to consider displaying its HTA licence in a more public area so that it may be seen easily by visitors. This may help the establishment in assuring the public about the display of human tissue, the regulation of this activity and the standards that establishments must meet in order to perform this activity. This may, in turn, support public confidence regarding the public display of human tissue and in informing them that it is governed by statutory regulation in order to ensure the safe and ethical use of human tissue.

Concluding comments

Areas of good practice were observed during the inspection and some examples have been included below:

- The establishment has developed a detailed statement regarding the display of the human tissue which includes some background about the establishment, the donor consent that was sought and regulation by the HTA. Should the establishment have any enquiries from the public it can provide a copy of this statement in addition to speaking with them, which may help in answering some of the public's questions.

- The establishment undertakes daily checks on the condition of the human tissue before the exhibition gallery opens to the public. The condition checks are undertaken twice each day, firstly by the maintenance team which checks for signs of damage to the tissue container or loss of preservation fluid and records the visual checks as part of the daily task check list. Additional checks are then undertaken by the exhibition staff as they prepare the gallery for the public. Both of these checks help to assure the Designated Individual that any deterioration of the tissue or damage to the display cabinet will be identified.

- The Designated Individual sits on multiple committees at the establishment, each dealing with a different area of the establishment's governance. These committees include the health and safety committee, the crisis management group and the exhibits maintenance group. Each of these group's activities cover aspects relating to the public display of tissue such as incidents, and training. Being on each of these groups helps the Designated Individual in maintaining oversight of any incidents or maintenance issues relating to the tissue.

The HTA has given advice to the Designated Individual with respect to consent (should any consent for public display be sought in the future), staff training and risk assessments. More general advice regarding the display of the HTA licence has also been given.

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

Report sent to DI for factual accuracy: 31 October 2017

Report returned from DI: 24 November 2017

Final report issued: 6 December 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 have been excluded.

HTA licensing Standards: Public Display sector

Consent

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in its codes of practice

a) If the establishment is required to seek consent, a process is in place which is in accordance with the requirements of the HT Act and the HTA's Codes of Practice, and records of consent are maintained.

b) If relevant, there is training for staff on how to seek consent for the public display of human material, which addresses the requirements of the HT Act and the HTA's Codes of Practice and records demonstrate attendance.

c) Where applicable, there are agreements with other parties to ensure that consent is sought in accordance with the requirements of the HT Act and the HTA's Codes of Practice.

Guidance

Establishments should seek to receive written assurance that, for imported specimens, the donor's consent was sought in line with that country's requirements

C2 Information about the consent process and the activity for which consent is sought is provided

a) There is written information about the consent process for those giving consent, which reflects the requirements of the HT Act and its codes of practice

b) Standard operating procedures (SOPs) specify how information on consent is provided.

Governance and quality systems

GQ1 All aspects of the establishment's work are governed by documented policies and procedures

a) There are collections management policies and procedures, or equivalent, governing the storage and public display of bodies and human tissue which give due regard to the dignity of the deceased. These should include, as relevant to the establishment's activities:

   i. an overarching policy on the care and treatment of exhibits containing human tissue;

   ii. seeking consent for donation of bodies and human tissue for public display;

   iii. specimen acquisition e.g. by bequest, exchange, loan or purchase from another individual or organisation nationally or internationally;

   iv. specimen preservation, monitoring and conservation;

   v. control of environmental conditions;

   vi. the management of sensitive material, such as fetal remains;

   vii. transportation of specimens e.g. on loan to or return to other collections;

   viii. the disposal/deaccession of specimens;

   ix. storage contingency arrangements;

   x. the creation, amendment, retention and destruction of records;

   xi. the management of incidents and complaints.

   Guidance

   Individual SOPs for each activity are not required; some SOPs will cover more than one activity. Where appropriate, procedures should be developed in consideration of potential risks. For example, where staff undertake cleaning of material on public display, the procedure should be based on the assessment of risk to staff from contamination and the cleaning materials they will be exposed to, as well as the potential risk of damage to the item being cleaned.

b) There are procedures that govern the work of temporary staff and contractors, which ensure that they are sensitive to the special status of human remains and exhibits consisting of human material.

c) Regular governance meetings are held; for example, health and safety and risk management committees, that have agendas and minutes.

   Guidance

Team meetings provide an ideal opportunity to pass on relevant information to staff working under the licence, as well as allowing them to raise any issues or concerns.

d) Policies and procedures are reviewed regularly and are version controlled.

Guidance

Governance documentation should be up to date, subject to regular review and reflective of good practice, including guidance from organisations such as Arts Council England and the Department for Culture, Media and Sport (DCMS).

GQ2 There is a documented system of audit

a) There is a documented system of audit, which includes records of traceability and specimens.

Guidance

Audits should include compliance with documented procedures; the completion of records; and traceability

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

a) There are clear reporting lines and accountability, and documented roles and responsibilities.

b) There is documented induction and training for staff, which includes the handling of human remains; attendance at training is recorded.

GQ4 There is a systematic and planned approach to the management of records

a) There are suitable systems for the creation, review, amendment, retention and destruction of records.

b) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

GQ5 There are systems to ensure that untoward incidents are investigated promptly

a) There is a system for reporting and investigating serious untoward incidents.

Guidance

This should include incidents relating to the safety and integrity of human material and those that may impact on the establishment's ability to meet the requirements of the HTA codes of practice and licensing Standards. Staff should understand what is meant by an incident and be familiar with the procedure to follow when such an incident occurs.

Serious incidents should be reported to the HTA.

b) Corrective and preventive actions are taken where necessary and improvements in practice are made.

GQ6 Risks associated with the establishment's practices and processes in relation to the storage and display of human material are assessed and monitored

a) Risk assessments are documented.

Guidance

Risk assessments should consider risks to, for example: tissue traceability; storage of specimens; and dignity of the deceased. Where actions are identified to mitigate risks, these should have deadlines for completion and a person responsible for completing them.

For risk assessments to be meaningful, they should be undertaken by a suitably trained person, who has an objective view or who is following an established risk-assessment process. It may not be appropriate for staff working under the authority of the licence to undertake their own risk assessments. In any event, the results of risk assessments should be shared with staff so that they have an understanding of the issues identified.

b) Risk assessments set out steps taken to mitigate risks

c) Risk assessments are reviewed regularly

Guidance

Risk assessments should be reviewed every 1-3 years

d) Staff can access risk assessments and are made aware of them in training

Traceability

T1 A coding and records system facilitates traceability of bodies and human tissue

a) Bodies and human tissue are traceable through a unique identification number or code.

Guidance

Procedures relating to indexing and record-keeping should reference the establishment's system of labelling bodies and body parts.

b) The system of record-keeping should include the location of material at the establishment and may include a description or photographic record and details of any specialist storage conditions, shelf-life or contamination risk.

T2 Records of traceability are maintained

a) Records of receipt, storage, transportation and delivery of bodies and human tissue are maintained.

b) Disposal or de-accession records include the date, reason and method of disposal/de-accession.

Guidance

If relevant material is loaned to, or borrowed from, another licensed establishment, consideration should be given to minimising the likelihood of theft or damage during transport. Loan agreements should define how the material is preserved and any potential contamination risks associated with it. There should be clear instructions on how to deal with an untoward incident and contact details for the person responsible at the establishment loaning relevant material.

c) Where applicable, disposal arrangements reflect specified wishes of the donor.

Premises, facilities and equipment

PFE1 The premises and facilities are secure and safeguard the dignity of the deceased and the integrity of human tissue

a) Areas used for storage or public display provide an environment that is safe for staff and visitors and preserves the integrity of the material and the dignity of the deceased.

Guidance

As advised in the DCMS Guidance for the care of human remains in museums*, visitors should not come across human remains unaware. The establishment should give consideration to suitable signage, explaining the presence of bodies, body parts or other relevant material and the requirement to treat them with dignity and respect.*

b) The establishment is clean, well maintained and subject to a programme of planned preventative maintenance.

c) Staff have access to the protective clothing, materials and equipment they need.

d) A documented risk assessment has been carried out of the premises to ensure that they are appropriate for the licensed activities.

Guidance

An assessment can cover such risks as fire, theft and vandalism.

e) There are policies in place to review and maintain the safety of staff and visitors.

f) The premises are secure with controlled access to bodies, human tissue and records.

g) Security measures include the use of lockable display areas and alarm systems.

PFE2 There are appropriate facilities for the storage of bodies and human tissue

a) Where chemicals are used for preservation, the area is adequately ventilated to control exposure.

Guidance

Control of Substances Hazardous to Health (COSHH) regulations require the exposure of formaldehyde to be controlled as low as possible and below the maximum exposure limit (2 ppm). This may include regular monitoring of formaldehyde levels and continuous operation of extract ventilation.

b) Critical storage conditions are monitored and recorded

Guidance

This could include, for example, temperature; humidity, dust or light levels, in storage and display areas.

c) There are systems to deal with emergencies.

Guidance

This could include, for example, fire, flood, power failure or public disturbance.

d) There is a documented contingency plan for storage of bodies and human tissue.

Guidance

For example, the establishment could have arrangements for material to be transferred to alternative licensed premises.

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.