Site visit inspection report on compliance with HTA minimum standards

International Centre for Life

HTA licensing number 12644

Licensed under the Human Tissue Act 2004 for the

- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose; and**
- **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**

24 May 2016

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.

The International Centre for Life (the establishment) was found to have met all HTA standards.

The HTA has given advice to the Designated Individual with respect to audits and planning for any future public display events that may take place.

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, 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

The International Centre for Life (the establishment) has been licensed since February 2016 for the storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose; and 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. This site-visit inspection was to assess whether the establishment meets the HTA's standards. The timetable for the site visit was developed in consideration of the compliance information submitted upon application for the licence and pre-inspection discussions with the DI.

The establishment has been licensed previously, between April 2014 and January 2015, for the same licensable activities under licensing number 12612. During this previous licenced period, the establishment hosted the 'Body Worlds Vital exhibition' consisting of twelve plastinated human bodies and approximately two hundred smaller plastinated specimens. All specimens originated from the Institute for Plastination in Germany. When the temporary exhibition ended and returned overseas, the establishment was not storing or using any relevant material and it revoked its HTA public display licence.

The establishment is now hosting another temporary exhibition of material originating from the Institute for Plastination, and this inspection was scheduled to coincide with the setting up of the 'Animal Inside Out' exhibition, three days before it opened to the public. Although predominantly an exhibition of plastinated animal tissue, one whole plastinated human body and 15 smaller plastinated human tissue specimens are on display.

The inspectors met with staff overseeing and curating the exhibition, carried out a visual inspection of the area where specimens are on display and reviewed documentation relating to licensable activities. In addition to the temporary exhibition, the establishment has installed a permanent exhibition, the 'Brain Zone', which includes the display of a plastinated human brain provided by the Institute for Plastination. The plastinated brain is contained in a tamper-proof display case within a dedicated area of the Brain Zone. The Brain Zone and area where the brain is on display were visited and documentation relating to the permanent exhibit was also reviewed during the inspection.

The consent requirements of the Human Tissue Act 2004 do not apply to imported specimens. Although the standards on consent are therefore not applicable, the HTA considers it good practice for establishments involved in public display to put in place effective and reliable processes to provide assurance that imported human tissue is obtained in the source country with valid consent. During the inspection, the consent policy of the Institute for Plastination was reviewed along with example donor consent forms. The consent policy and the agreement between the Institute for Plastination and the establishment state that all donations are compliant with relevant local laws. Additionally, within the Brain Zone, an anonymised copy of the actual consent form completed by the donor of that tissue is included in the display.

Staff at the establishment are not involved in setting up the exhibition of plasitnated tissue, as this is undertaken by staff from the Institute for Plastination. Equally, when the Animal Inside Out exhibition ends, the Institute for Plastination staff will return to dismantle the exhibition, package the specimens and transport them to the next venue. Establishment staff are trained by the DI in any cleaning of the exhibits that may be required during the exhibition. Additionally, establishment staff receive training on what to do if an adverse event relating to the specimens on display occurs, how to answer questions from the public about the exhibition and the source of the items and on the expected behaviours of visitors with regards to the specimens, including, for example, photography.

Despite the large size of the display area, being mindful of the sensitive nature of exhibits comprising human tissue, the establishment has endeavoured to ensure that the specimens are not viewable from outside the 'Animal Inside Out' exhibition in other areas of the establishment's premises. During the inspection, the HTA inspectors identified a vantage point from which the plastinated human body could be seen from outside of the exhibition. Establishment staff reacted quickly, installing a curtain to permanently block this view.

The HTA standards on disposal do not currently apply to the establishment as the human tissue specimens making up the exhibition will be returned to the Institute for Plastination at the end of the exhibition or if they are damaged in some way during the exhibition.

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	Although there are daily checks of the exhibitions undertaken by establishment staff, the DI is advised to implement a regular review of the human tissue specimens on display using the Institute for Plastination's photographic inventory as a reference. This will assist the DI with the on-going monitoring of the condition of the exhibits and facilitate early identification of any issues..
2.	General	The establishment currently only exhibits specimens from the Institute for Plastination. Although the visiting 'Animal Inside Out' exhibition is only temporary, the establishment's Brain Zone, where a plastinated human brain is on display, will remain. The establishment will maintain its HTA public display licence so that it remains appropriately licensed for the public display of human tissue. Since it will have an HTA public display licence, the DI may, at some point in the future, put additional specimens on display or use them during public scientific demonstrations. The DI is advised to document how the establishment would assess the suitability of such future displays of human tissue and how it would assure itself that it continues to meet the HTA standards, for example, by ensuring appropriate and valid donor consent for the activity is in place. Should the DI seek to host any future public display events at the establishment, they are advised to contact the HTA for further advice if needed.

Concluding comments

Areas of good practice were observed during the inspection, examples of which are set out below.

The establishment had undertaken a detailed risk assessment of the permanent display of human tissue, the Brain Zone, which included not only the physical risks to the tissue but also wider risks related to the dignity of the deceased. An example of this was the assessment of a risk that the tissue or the donor be represented in a disrespectful manner.

The HTA has given advice to the Designated Individual with respect to audits and planning for any future public display events that may take place.

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

Report sent to DI for factual accuracy: 21 June 2016

Report returned from DI: 22 July 2016

Final report issued: 18 July 2016

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.

Governance and quality system standards
GQ1 The establishment's work on public display is supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, governing the storage and public display of bodies and relevant material • There is a system of risk management in place • Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes • There is a complaints system in place
GQ2 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
• Qualifications of staff and training is recorded • There are orientation and induction programmes for new staff • There is a documented training programme (e.g. health and safety, fire, risk management, infection control), including developmental training
GQ3 There is a systematic and planned approach to the management of records
• There are documented procedures for the creation, amendment, retention and destruction of records • There is regular audit of record content to check for completeness, legibility and accuracy • There is a back-up / recovery facility in the event of loss of records • Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)
GQ4 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 specimen, and to each of the products associated with it
GQ5 There are systems to ensure that all adverse events are investigated promptly
• There is a system for reporting adverse events • Corrective and preventive actions are taken where necessary and improvements in practice are made

GQ6 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
• There are 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 licensed activities • There are policies in place to review and maintain the safety of staff, students and visitors • Where appropriate, policies are in place to ensure that the premises are of a standard that ensures the dignity of the deceased • 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 Equipment is appropriate for use and environmental controls are in place to avoid potential contamination
• There are documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • There is a contingency plan for equipment failure
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells.
• Bodies and relevant material are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Critical storage conditions are monitored and recorded • There are systems to deal with emergencies out of hours
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
• A system is in place to ensure that traceability of specimens is maintained during transport • Records of transportation and delivery are maintained • Records are kept of any agreements with courier or transport companies

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.