Licence application assessment visit report on compliance with HTA licensing standards
Site visit date: **18 March 2024**

Barbican Art Gallery
Proposed HTA licensing number 12775

Application for a licence under the Human Tissue Act 2004

Activities applied to be licensed

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	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
Barbican Art Gallery	Applied to be licensed	Applied to be licensed

Summary of visit findings

The HTA found the proposed Designated Individual (DI) and the proposed Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

The Barbican Art Gallery (the establishment) was found to have met all HTA standards.

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	GQ3(b)	The proposed DI is advised to review the information provided to staff performing licensable activities to help to ensure that they have sufficient understanding and knowledge of the requirements of the Human Tissue Act 2004 and HTA's Codes of Practice.
2.	GQ6(a)	The establishment is advised to review and update risk assessments prior to displaying any relevant material in the gallery.
3.	General	The establishment only displays artwork on loan as part of planned temporary exhibitions. The establishment will maintain its HTA public display licence so that it remains appropriately licensed for the public display of human material. Should the proposed DI seek to host any future exhibitions with artwork containing human material, they are advised to contact the HTA for further advice if needed.

Background

The Barbican Art Gallery has an exhibition programme of modern and contemporary art, architecture, design and fashion which relies on loans from a wide range of international lenders. The establishment has applied for a HTA licence for the storage of relevant material and the use for the purpose of public display in order to display artwork containing human remains.

Description of activities undertaken during visit

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the inspection:

Standards assessed against during visit
28 of the 36 HTA licensing standards were covered during the assessment (standards published 3 April 2017). Some standards relating to consent procedures, C1(a)and C1(b), and standards relating to consent training, C2(a) and C2(b), were not applicable as the establishment does not directly seek consent from donors. Standards relating to disposal, T2(b) and T2(c) were not applicable, as the establishment only intends to temporarily loan artwork containing relevant material and therefore all artworks will be returned to the owner/ artist after the exhibitions. Furthermore, standards relating to critical storage conditions and chemicals, PFE2(a) and PFE2(b), were not applicable for the type of artwork the establishment intends to display.

Review of governance documentation
The overarching policy and procedural document relating to licensable activities was reviewed which included information on consent, staff training, responsible persons, traceability and adverse incidents. Risk assessments were also reviewed.

Visual inspection
A visual inspection of the site was conducted which included the primary storage area and gallery display locations.

Meetings with establishment staff
The inspection included discussions with staff carrying out processes under the licence. This included the Senior Manager of Exhibitions and Partnerships, and the Deputy Head of Visual Arts who is the proposed DI.

Report sent to proposed DI for factual accuracy: 25 March 2024

Report returned from proposed DI: No factual accuracy or request for redaction comments were made by the proposed DI

Final report issued: 27 March 2024

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI 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 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.

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.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence;
   - 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;
   - A notice of suspension of licensable activities;
   - Additional conditions being proposed, or;
   - 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 Codes of Practice, 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 review or at the time of the next 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 the final inspection report. Establishments 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 routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.