

Reference document – Public Display sector



IMPORTANT NOTE:

Please use Internet Explorer to access the online form. Other browsers may not support the software used.

The form must be completed in one session. Unfortunately there is no option to save it as you work. Please do not close your internet browser while you are completing this form as all your data will be lost.

We suggest that you have all the required information available to refer to when completing the online form. Details of how to access the form are provided at the end of this reference document.

Who should complete this form?

- Any establishment in the Public Display sector which holds an HTA licence is required to complete and submit this form.
- If an establishment holds more than one HTA licence, a separate form must be completed for each one (Anatomy, Post Mortem or Research).
- Anyone working under an HTA licence can complete the form; however, Designated Individuals must ensure that all required information is complete and accurate before submitting it to the HTA.

Further information is available from: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/htalegaldirections.cfm>

Purpose of the self assessment

The information gathered from this form will provide us with an update on how establishments meet HTA standards; the additional details about licensing activities being undertaken and responses to sector-specific questions will inform our risk assessments. The HTA will use the information gathered to inform the scheduling of site-visit inspections. It will also be used to guide our regulatory approach to each sector.

It is therefore important that your self assessment is completed accurately and reflects current systems and practices at your establishment.

Guidance is provided throughout the self assessment in the column to the right of the page.

SECTOR	TOTAL NUMBER OF PAGES TO COMPLETE	ESTIMATED TIME TO COMPLETE
ANATOMY	11 PAGES	45 minutes
POST MORTEM	9 PAGES	45 minutes
PUBLIC DISPLAY	11 PAGES	45 minutes
RESEARCH	10 PAGES	45 minutes

DEADLINE: Please ensure your self assessment form is submitted to us no later than Thursday 30 June 2011.

If you have any technical problems using the online form please contact our main telephone number (020 7269 1900) and ask to speak to our IT team.

For any questions regarding the form content please contact (020 7269 1900 or enquiries@hta.gov.uk) regarding your enquiry.

Preview of online form sections and questions

INFORMATION ABOUT YOUR ESTABLISHMENT: Public Display

Please ensure you select the correct sector on the online form as you will then answer the correct self assessment questions.

Sector details:	<p style="text-align: center;">GUIDANCE</p> <p>Please select your sector. This will ensure you are completing the correct form for your establishment.</p> <p style="text-align: center;">All sections marked with * must be completed.</p>
* Please indicate which sector your establishment is licensed under:	

Named persons working under the licence:	GUIDANCE All sections marked with * must be completed. Please complete this section for your main site / hub (if there are satellite sites). Please provide the Name(s) and job title(s) of Persons Designated.
* Name of Designated Individual: * Job title: * Number of Persons Designated at this site: Names and job titles of Persons Designated at this site:	

If your establishment has been or is due to be inspected or audited by any independent agencies (excluding the Human Tissue Authority), please list them below and include the date of the visit:	GUIDANCE

* Please confirm the licensable activities being undertaken at your establishment:	GUIDANCE Please tick all licensable activities that take place at your main site / hub. All sections marked with * cannot be left blank.
A 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	
B Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose	

<p>If human tissue is stored under your establishment's licence, at either the main site / hub or satellite sites, please indicate the scheduled purpose(s) for which the tissue may be used:</p>	<p style="text-align: center;">GUIDANCE</p> <p style="text-align: center;">Please tick all scheduled purposes that apply for the relevant material stored at your establishment</p>
Anatomical examination	
Clinical audit	
Determining the cause of death	
Education or training relating to human health	
Establishing after a person's death the efficacy of any drug or other treatment administered to him	
Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)	
Performance assessment	
Public display	
Public health monitoring	
Quality assurance	
Research in connection with disorders, or the functioning, of the human body	

<p>Satellite sites:</p>	<p style="text-align: center;">GUIDANCE</p> <p style="text-align: center;">All sections marked with * must be completed.</p> <p style="text-align: center;">See section above for licensable activities.</p>
<p>* Number of satellite sites:</p>	
<p>For each satellite site, please provide the following details:</p> <ul style="list-style-type: none"> • Satellite name and address • The licensable activities carried out at each satellite site (indicate A and /or B as 	

defined above) <ul style="list-style-type: none"> The details of Person Designated at each satellite site (Name and job title) 	
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SELF ASSESSMENT AGAINST HTA STANDARDS: Public Display

For this section, you will need to rate your establishment against HTA standards:

- Consent
- Governance and Quality Systems
- Premises, Facilities and Equipment
- Disposal

Ratings:

- (4) Fully met
- (3) Almost met
- (2) Partially met
- (1) Not met
- Not applicable

Consent standards

Standards	Self-rating	Guidance
* 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		<p style="text-align: center;">All sections marked with * must be completed. The examples given below for each standard are to help you make evidence-based judgments about the extent to which you meet each standard.</p> <p>Examples for C1:</p> <ul style="list-style-type: none"> Consent forms comply with the HTA's Codes of Practice If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act and the HTA's Codes of Practice, and records of consent are maintained Where applicable, there are agreements with third parties to

		ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice
* C2 Information about the consent process is provided and in a variety of formats		<p>Examples for C2:</p> <ul style="list-style-type: none"> • Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties who provide material for public display contain information about consent requirements
* C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent		<p>Examples for C3:</p> <ul style="list-style-type: none"> • Standard operating procedures (SOPs) detail the consent process • There is evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained
If any of the Consent standards are not applicable, please indicate which standard and why:		

Governance and quality systems (GQS) standards

Standards	Self-rating	Guidance
		<p>All sections marked with * must be completed.</p> <p>The examples given below for each standard are to help you make evidence-based judgments about the extent to which you meet each standard.</p>
* GQ1 The establishment's work on public display is supported by ratified documented policies and procedures as part of the overall governance process		<p>Examples for GQS1:</p> <ul style="list-style-type: none"> • 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

<p>* GQ2 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills</p>		<p>Examples for GQS2:</p> <ul style="list-style-type: none"> • 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
<p>* GQ3 There is a systematic and planned approach to the management of records</p>		<p>Examples for GQS3:</p> <ul style="list-style-type: none"> • 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)
<p>* GQ4 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail</p>		<p>Examples for GQS4:</p> <ul style="list-style-type: none"> • 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
<p>* GQ5 There are systems to ensure that all adverse events are investigated promptly</p>		<p>Examples for GQS5:</p> <ul style="list-style-type: none"> • There is a system for reporting adverse events • Corrective and preventive actions are taken where necessary and improvements in practice are made
<p>* GQ6 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately</p>		<p>Examples for GQS6:</p> <ul style="list-style-type: none"> • 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
<p>If any of the GQS standards are not applicable, please indicate which standard and why:</p>		

Premises, facilities and equipment (PFE) standards

Standards	Self-rating	<p style="text-align: center;">Guidance</p> <p style="text-align: center;">All sections marked with * must be completed. The examples given below for each standard are to help you make evidence-based judgments about the extent to which you meet each standard.</p>
<p>* PFE1 The premises are fit for purpose</p>		<p>Examples for PFE1:</p> <ul style="list-style-type: none"> • 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
<p>* PFE2 Equipment is appropriate for use and environmental controls are in place to avoid potential contamination</p>		<p>Examples for PFE2:</p> <ul style="list-style-type: none"> • 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
<p>* PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells.</p>		<p>Examples for PFE3:</p> <ul style="list-style-type: none"> • 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

<p>* PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination</p>		<p>Examples for PFE4:</p> <ul style="list-style-type: none"> • 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
<p>If any of the PFE standards are not applicable, please indicate which standard and why:</p>		

Disposal standards

Standards	Self-rating	Guidance
<p>* D1 There is a clear and sensitive policy for disposing of human organs and tissue</p>		<p>Examples for D1:</p> <ul style="list-style-type: none"> • There is a documented disposal policy • There is compliance with health and safety recommendations
<p>* D2 The reason for disposal and the methods used are carefully documented</p>		<p>Examples for D2:</p> <ul style="list-style-type: none"> • There is a system for tracking the disposal of relevant material, including recording the method and reason for disposal • Where applicable, disposal arrangements reflect specified wishes
<p>If any of the Disposal standards are not applicable, please indicate which standard and why:</p>		

ADDITIONAL QUESTIONS: Public Display

<p>1. * Please describe the Designated Individual's role in governance and quality management systems</p> <p>Takes the lead in management of governance and quality systems, with support from other members of staff</p> <p>Some involvement in management of governance and quality systems, in addition to delegating responsibilities to other members of staff</p> <p>Limited time to spend on governance and quality systems</p> <p>No involvement in governance and quality systems</p>	<p>QUESTION GUIDANCE</p> <p>This question refers to the involvement of the DI in day to day quality management within your establishment.</p> <p>Please select one option for this question. All sections marked with * must be completed.</p>
<p>2. * Do you have sufficient staff to monitor visitors and carry out your licensable activities without concerns?</p> <p>Yes</p> <p>No</p>	<p>QUESTION GUIDANCE</p> <p>This question asks if you have sufficient number of staff to monitor visitors during busy periods as well as during quiet times to ensure that items are not tampered with or damaged.</p> <p>Please select one option for this question. All sections marked with * must be completed.</p>
<p>3. * Which of the following best describes staff working at the establishment</p> <p>All staff are employed by the establishment (licence holder)</p> <p>Some external staff work at the establishment, are trained by the establishment, and follow the establishment's procedures</p> <p>Some external staff work at the establishment and they do not receive training but are provided with documented procedures for reference.</p>	<p>QUESTION GUIDANCE</p> <p>This refers to arrangements in place to ensure the safety of items being stored and / or exhibited.</p> <p>Please select one option for this question. All sections marked with * must be completed.</p>

<p>4. * How many items, i.e. bodies, body parts and other items of human tissue, are currently on display?</p> <table border="1"> <tr><td>None</td></tr> <tr><td>1 - 20</td></tr> <tr><td>21 - 100</td></tr> <tr><td>101 - 1000</td></tr> <tr><td>More than 1000</td></tr> </table>	None	1 - 20	21 - 100	101 - 1000	More than 1000	<p style="text-align: center;">QUESTION GUIDANCE</p> <p style="text-align: center;">Please select one option for this question. All sections marked with * must be completed.</p>
None						
1 - 20						
21 - 100						
101 - 1000						
More than 1000						
<p>5. If you have selected 'none' for question 4, is your collection only made up of stored archival material which you do not intend to display?</p> <table border="1"> <tr><td>Yes</td></tr> <tr><td>No</td></tr> </table>	Yes	No	<p style="text-align: center;">GUIDANCE</p> <p>A licence is not required to store items in a museum archive when there is no intention of displaying them to the public. A licence is required if those items will be used for public display.</p> <p style="text-align: center;">Please select one option for this question.</p>			
Yes						
No						
<p>6. If you are storing items i.e. bodies, body parts and other items of human tissue, how many are kept in storage for display in the future?</p> <table border="1"> <tr><td>None</td></tr> <tr><td>1 - 20</td></tr> <tr><td>21 - 100</td></tr> <tr><td>101 - 1000</td></tr> <tr><td>More than 1000</td></tr> </table>	None	1 - 20	21 - 100	101 - 1000	More than 1000	<p style="text-align: center;">QUESTION GUIDANCE</p> <p style="text-align: center;">Please select one option for this question.</p>
None						
1 - 20						
21 - 100						
101 - 1000						
More than 1000						
<p>7. * Do you store or display items of human tissue from other establishments?</p> <table border="1"> <tr><td>Yes, and documented agreements are in place as required by the HTA's Code of Practice 7 - Public Display</td></tr> <tr><td>Yes, but no documented agreements are in place</td></tr> </table>	Yes, and documented agreements are in place as required by the HTA's Code of Practice 7 - Public Display	Yes, but no documented agreements are in place	<p style="text-align: center;">QUESTION GUIDANCE</p> <p style="text-align: center;">This refers to whether you store or display items from other establishments and if you have any formal agreements to cover these arrangements.</p> <p style="text-align: center;">Please select one option for this question.</p>			
Yes, and documented agreements are in place as required by the HTA's Code of Practice 7 - Public Display						
Yes, but no documented agreements are in place						

<input type="text" value="No"/>	<p>All sections marked with * must be completed. This link opens in a separate window: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm</p>
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<p>8. * Do you display items at your licensed premises only?</p> <p> <input type="text" value="Yes"/> <input type="text" value="No"/> </p> <p>If you display, or have previously displayed items away from your licensed premises, please provide details below, including the name of the establishment and the material displayed:</p>	<p>QUESTION GUIDANCE</p> <p>This refers to whether or not you display items at other locations. Please select one option for this question.</p> <p>All sections marked with * must be completed.</p>
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<p>9. Which, if any, of the following items do you display?</p> <table border="1" data-bbox="248 820 1088 1046"> <tr><td><input type="checkbox"/> Whole body or bodies</td></tr> <tr><td><input type="checkbox"/> Whole organs</td></tr> <tr><td><input type="checkbox"/> Plastinated bodies, body parts or organs</td></tr> <tr><td><input type="checkbox"/> Fetal material</td></tr> <tr><td><input type="checkbox"/> Tissue from children</td></tr> <tr><td><input type="checkbox"/> Small pieces of tissue or microscope slides</td></tr> </table>	<input type="checkbox"/> Whole body or bodies	<input type="checkbox"/> Whole organs	<input type="checkbox"/> Plastinated bodies, body parts or organs	<input type="checkbox"/> Fetal material	<input type="checkbox"/> Tissue from children	<input type="checkbox"/> Small pieces of tissue or microscope slides	<p>QUESTION GUIDANCE</p> <p>This will help to inform the HTA of the type of items you display.</p> <p>Please tick all that are applicable.</p>
<input type="checkbox"/> Whole body or bodies							
<input type="checkbox"/> Whole organs							
<input type="checkbox"/> Plastinated bodies, body parts or organs							
<input type="checkbox"/> Fetal material							
<input type="checkbox"/> Tissue from children							
<input type="checkbox"/> Small pieces of tissue or microscope slides							

<p>10. * Do you import bodies, body parts and relevant material from other countries?</p> <p> <input type="text" value="Yes"/> <input type="text" value="No"/> </p> <p><input type="text" value="If you have answered 'yes', what steps do you take to assure yourself that imported material was obtained ethically and legitimately?"/></p>	<p>QUESTION GUIDANCE</p> <p>This question refers to the steps you take to assure yourself that imported items are obtained ethically and legitimately in line with local requirements.</p> <p>Please select one option for this question. All sections marked with * must be completed.</p>
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Do you review consent documentation for each of the items?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Do you review information on consent provided to donors?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Please describe any other steps which you take to assure yourself that consent is in place:		
<input type="text"/>		

11. * Do you transfer relevant material to other locations?

Yes, and documented agreements are in place as required by the HTA's Code of Practice 7 - Public Display
Yes, but not all required agreements and documentation are in place
No

QUESTION GUIDANCE

This question refers to transportation of items and agreements you have with transport companies.

Please select one option for this question.
All sections marked with * must be completed.

This link opens in a separate window:
<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm>

12. * Have you had any adverse incidents relating to bodies, body parts or items of human tissue during the last twelve months?

Yes
No

If you have answered 'yes', please provide a brief summary of the nature of the

QUESTION GUIDANCE

Please select one option for this question.

All sections marked with * must be completed.

Adverse incidents could include:

<p>incident(s) and any corrective and preventative actions which were put in place:</p>	<ul style="list-style-type: none"> • theft, loss, or damage of items by visitors or staff • mislabelling of items • loss of records • loss of items during transportation <p>Please include a very brief summary of the incident, including corrective actions and steps taken to ensure it does not happen again.</p>
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Submission instructions

Once you have completed your online form, you will be able to review your self assessment before you submit it to the HTA. Please make sure that all mandatory questions (indicated with *) have been answered. We will need to contact you if any of these are submitted without an answer.

Before you submit your self assessment, please print a copy for your records. If you are not the Designated Individual (DI), please ensure a copy is provided to the DI.

What happens next?

- Your form will be securely submitted to the Human Tissue Authority.
- You will receive an email (to the email address provided on the first page of the form) which will contain a copy of your submission.

If you are not the Designated Individual (DI), please ensure a copy is provided to the DI.

To complete your self assessment online, please access the [online form](#) (HTA-01-002/2010)