

## Reference document – Post Mortem 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 Post Mortem 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, Public Display 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](mailto:enquiries@hta.gov.uk) ) regarding your enquiry.*

### **Preview of online form sections and questions**

#### **INFORMATION ABOUT YOUR ESTABLISHMENT: Post Mortem**

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

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

<b>Details of the person completing this self assessment:</b>		<p style="text-align: center;"><b>GUIDANCE</b></p> <p>All sections marked with * must be completed.</p> <p>Please provide your work job title.</p> <p>Please provide your role with respect to the HTA licence e.g. Person Designated.</p> <p>Please provide us with your work contact details so that we can contact you if there is a problem with your submitted form, e.g. a blank response to a question where further information may be required.</p>	
* Your title:	* Your first name:		* Your last name:
* Your job title:	* Your role with respect to the HTA licence:		
<b>Your contact details:</b>			
* Telephone number(s):	* Email address:		
* Address:			

<b>Establishment details (main site / hub):</b>		<p style="text-align: center;"><b>GUIDANCE</b></p> <p>Please complete this section for your main site / hub (hub if there are satellite sites).</p> <p>Please enter your licence number only. This can be found on your paper licence from the HTA.</p> <p>Generally the Licence Holder will be an organisation, such as an NHS Trust, University or museum.</p> <p>If the licence holder is an organisation e.g. a NHS Trust, the representative should be a named individual (Chief Executive, Medical Director etc.).</p> <p>All sections marked with * must be completed.</p>
* Establishment name:		
* HTA licensing number		
* Licence holder:		
Licence holder representative:		

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

<b>If your establishment is registered with CPA, please provide the following details:</b>	<b>GUIDANCE</b>  Clinical Pathology Accreditation (CPA)			
<b>Registration number:</b> <b>Current status:</b> <b>Date of last full assessment visit:</b> (DD-MM-YYYY)				
<table border="1" style="width: 100%;"> <tr> <td style="width: 80%;"><b>Was the mortuary included?</b></td> <td style="width: 20%; text-align: center;">Yes</td> </tr> <tr> <td></td> <td style="text-align: center;">No</td> </tr> </table> <b>Brief summary of findings:</b>		<b>Was the mortuary included?</b>	Yes	
<b>Was the mortuary included?</b>	Yes			
	No			

<b>* Please confirm the licensable activities being undertaken at your establishment:</b>		<b>GUIDANCE</b> Please tick all licensable activities that take place at your main site / hub.  All sections marked with * must be completed.
A	The making of a post mortem examination	

B	The removal from the body of a deceased person (otherwise than in the course of an anatomical examination or a post mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose	
C	The storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose	

<b>If tissue from living or deceased persons is stored under this licence, at either the main site / hub or satellite sites, please indicate to which scheduled purpose(s) the tissue may be used:</b>	<p><b>GUIDANCE</b></p> <p>Please do not include tissue from living persons which is being held as part of diagnostic activities.</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><b>* Do you routinely store tissue samples (blocks and / or slides) as part of the medical records of the deceased?</b></p> <table border="1" data-bbox="181 331 383 411"> <tr> <td data-bbox="181 331 383 371">Yes</td> </tr> <tr> <td data-bbox="181 371 383 411">No</td> </tr> </table>	Yes	No	<p style="text-align: center;"><b>GUIDANCE</b></p> <p>Please select the appropriate Yes or No option for this questions. All sections marked with * must be completed.</p> <p>The HTA considers that tissue stored as part of the medical record is being stored for potential use for a scheduled purpose and must therefore be stored, with appropriate consent, on licensed premises</p>
Yes			
No			

<p><b>Satellite sites:</b></p>	<p style="text-align: center;"><b>GUIDANCE</b></p> <p>All sections marked with * must be completed.</p> <p>See section at the top of the page for licensable activities.</p>
<p><b>* Total number of satellite sites:</b></p>	
<p><b>For each satellite site, please provide the following details:</b></p> <ul style="list-style-type: none"> <li>• Satellite name and full address</li> <li>• The licensable activities carried out at each satellite site (indicate A, B and C as defined above)</li> <li>• The details of Person Designated at each satellite site (Name and job title)</li> </ul>	

<p><b>If your establishment has unlicensed premises which are used to store bodies prior to post mortem examination or release for burial or cremation, please provide details of these premises below:</b></p>	<p style="text-align: center;"><b>GUIDANCE</b></p>
<p><b>Name and full address of site(s):</b></p>	

<b>In the space provided below, please list any areas outside the mortuary where:</b>	<b>GUIDANCE</b>
<p><b>A) removal of tissue takes place (including blood and urine) from deceased persons for use for scheduled purposes</b> (e.g. A&amp;E, maternity unit, paediatric ward, other wards)</p> <p><b>B) tissue from living or deceased persons is being stored for use for a scheduled purpose</b> (e.g. laboratory, designated storage areas)</p>	
<p>DI's should check with staff in non-mortuary areas before responding to this question.</p> <p>Scheduled purposes are listed on the previous page.</p> <p>If removal and storage do not take place outside of the mortuary, enter 'N/A'</p>	

<b>If you have indicated in (A), above, that removal of tissue from the deceased takes place outside the mortuary; please provide the details of the Persons Designated (Name and job title) in each of these areas, in the space below:</b>	<b>GUIDANCE</b>
<p>Please provide the Name(s) and job title(s) of Persons Designated.</p>	

### ADDITIONAL QUESTIONS: Post Mortem

<p>1. * a. Do you share governance and / or a quality management system with any other licensed establishment?</p> <p style="text-align: right;">Yes No</p> <p>* b. Do staff employed at your establishment work at any other licensed establishment (this includes the Designated Individual, Anatomical Pathology Technologists and Pathologists)?</p> <p style="text-align: right;">Yes No</p> <p>* c. Do you send bodies to other establishments for post mortem examination?</p> <p style="text-align: right;">Yes No</p> <p>* d. Do you send whole organs and / or tissues to other establishments for analysis and examination?</p> <p style="text-align: right;">Yes No</p>	<p><b>QUESTION GUIDANCE</b></p> <p>Please select the appropriate Yes or No option for these questions. All sections marked with * must be completed.</p>
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* e. Do you receive bodies from other establishments for post mortem examination?	Yes
	No
* f. Do you receive whole organs and / or tissues from other establishments for analysis and examination?	Yes
	No

Your establishment may have links with other HTA-licensed establishments. If you have answered 'Yes' to any of the questions above, please provide the name and full address of the establishment(s):

**2. \* Do any staff not employed by your establishment carry out the following activities at your establishment?**

* a. Post mortem examination	Yes
	No
* b. Removal of organs and / or tissue for the purpose of transplantation	Yes
	No
* c. Removal of organs and / or tissue for the purpose of research	Yes
	No

If you have answered 'Yes' to any of the above questions, please provide job titles and organisation details below:

**QUESTION GUIDANCE**

Please select the appropriate Yes or No option for these questions.

All sections marked with \* must be completed.

Staff who are not employed by your establishment may be from an NHSBT retrieval team or be a Home Office pathologist etc.

**3. If you answered 'Yes' to any of the options in question 2, do you have written agreements with the individuals or their organisations?**

Yes
No

**QUESTION GUIDANCE**

Question 2 relates to staff not employed by your establishment. There should be a written agreement that while they are working at the establishment, they will follow all local policies and procedures and undertake any training required.

<p>4. <b>* Do mortuary staff remove organs and / or tissue for use for transplantation either in the mortuary or in theatres?</b></p> <p>Yes No</p> <p>If you have answered 'Yes', please indicate who this is done for below: (e.g. CTS eye banks, NHSBT)</p>	<p style="text-align: center;"><b>QUESTION GUIDANCE</b></p> <p style="text-align: center;">This could be Anatomical Pathology Technologists or Pathologists</p> <p style="text-align: center;">Please select one option for this question. All sections marked with * must be completed.</p>
<p>5. <b>If you answered 'Yes' to question 4, do you have written agreements in place?</b></p> <p>Yes No</p>	<p style="text-align: center;"><b>QUESTION GUIDANCE</b></p> <p style="text-align: center;">There should be a written agreement that while they are working at the establishment, they will follow all local policies and procedures and adhere to any training provided.</p>
<p>6. <b>* Do mortuary staff remove organs and / or tissue for use for research either in the mortuary or in theatres?</b></p> <p>Yes No</p> <p>If you have answered 'Yes', please indicate who this is done for below: (e.g. individual researcher, research group or organisation)</p>	<p style="text-align: center;"><b>QUESTION GUIDANCE</b></p> <p style="text-align: center;">Please select one option for this question. All sections marked with * must be completed.</p>
<p>7. <b>* Do any non-mortuary staff remove tissue for research, for example surgeons in theatre?</b></p> <p>Yes No</p> <p>If you have answered 'Yes', are there written agreements in place that they will carry out the removal in accordance with the requirements under the PM licence?</p>	<p style="text-align: center;"><b>QUESTION GUIDANCE</b></p> <p style="text-align: center;">Please select one option for this question. All sections marked with * must be completed.</p>

<input type="checkbox"/> Yes <input type="checkbox"/> No	
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**8. \* Do any other staff, who are not directly managed within the mortuary, carry out tasks which relate to the licensed activities?**

Yes  
 No

**QUESTION GUIDANCE**

For example, nursing / ward staff, portering staff, laboratory staff, bereavement officers who may deliver, admit and / or release bodies; carry out viewings / identifications, arrange or manage transportation of organs and tissues

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

**9. If you answered “Yes” to question 8, how do you ensure that these individuals are familiar with mortuary policies and procedures in order to carry out this work correctly?**

Training is provided and attendance is documented  
 They are shown what to do by a member of mortuary staff but this is not documented  
 They are provided with policies and procedures and must sign to indicate that they have understood them  
 They are provided with policies and procedures to read.

**QUESTION GUIDANCE**

Please tick all that are applicable.

**10. \* Do you feel there are sufficient staffing levels at your establishment to allow you to carry out licensable activities without concerns?**

Yes  
 No

**QUESTION GUIDANCE**

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

11. \* Please describe the Designated Individual's role in governance and quality management systems by choosing one of the following:

a. Takes the lead in management of governance and quality systems, with support from other members of staff

b. Has some involvement in management of governance and quality systems, but delegates responsibilities to other members of staff

c. Has limited time to spend on governance and quality systems

d. Has no involvement in governance and quality systems

If you have selected option b, c or d, please provide the name and job title of the individual who oversees governance and quality management under the licence:

Please describe below how this individual is accountable to the Designated Individual:

### QUESTION GUIDANCE

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

For example if the individual reports directly to the DI or attends shared meetings etc.

12. Please indicate all types of PM examination carried out at your establishment:

**Coronial:**

Adult

Paediatric

High risk

Home Office / forensic

**Hospital:**

Adult

Paediatric

For any type of examination which you do not carry out, provide the name and full address of the establishment(s) to which you refer bodies in these cases:

### QUESTION GUIDANCE

Please tick all that are applicable.

<p><b>13. * Do you store material on behalf of any person, group or organisation?</b></p> <p>Yes <input type="text"/></p> <p>No <input type="text"/></p>	<p><b>QUESTION GUIDANCE</b></p> <p>For example, an individual researcher, a research group or another hospital. This does not include storage of material awaiting collection or transfer to a different establishment.</p> <p>Please select one option for this question. All sections marked with * must be completed.</p>
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<p><b>14. If you answered 'Yes' to question 13, do you have written agreements in relation to this storage?</b></p> <p>Yes <input type="text"/></p> <p>No <input type="text"/></p>	<p><b>QUESTION GUIDANCE</b></p> <p>Question 13 is regarding storage of material on behalf of an individual researcher, a research group or another hospital etc.</p>
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<p><b>15. * Do you release tissue to individual researchers, research groups or other organisations for research?</b></p> <p>Yes <input type="text"/></p> <p>No <input type="text"/></p>	<p><b>QUESTION GUIDANCE</b></p> <p>Please select one option for this question. All sections marked with * must be completed.</p>
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<p><b>16. If you answered 'Yes' to question 15, do you have generic research ethics committee (REC) approval?</b></p> <p>Yes <input type="text"/></p> <p>No <input type="text"/></p>	<p><b>QUESTION GUIDANCE</b></p>
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17. If you answered 'Yes' to question 15 but 'No' to question 16, do you have written agreements with individuals, groups and / or organisations to which you release tissue for research?

Yes

No

#### QUESTION GUIDANCE

18. \* Do you store fetal tissues or fetuses (products of conception, non-viable fetuses, whole fetuses)?

Yes

No

If you have answered 'Yes', please state where you hold these while they are awaiting release for burial /cremation or disposal:

#### QUESTION GUIDANCE

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

19. \* Are storage locations appropriately secured?

Yes

No

#### QUESTION GUIDANCE

Appropriately secured means that access to areas where licensable activity takes place is limited to authorised persons only.

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

### 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).