

Reference document – Anatomy 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 Anatomy 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 (Public Display, 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: Anatomy

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

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

licensed under:	
------------------------	--

Details of the person completing this self assessment:		<p>GUIDANCE</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>	
* Your title:	* Your first name:		* Your last name:
* Your job title:	* Your role with respect to the HTA licence:		
Your contact details:			<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>
* Telephone number(s):	* Email address:		
* Address:			

Establishment details (main site / hub):	<p>GUIDANCE</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>
* Establishment name:	
* HTA licensing number:	
* Licence holder:	

<p>Licence holder representative:</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>
--	---

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

<p>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:</p>	<p style="text-align: center;">GUIDANCE</p>

<p>* Please confirm the licensable activities being undertaken at your establishment:</p>	<p style="text-align: center;">GUIDANCE</p> <p>Please tick all licensable activities that take place at your main site</p> <p>All sections marked with * cannot be left blank.</p>	
<table border="1"> <tr> <td data-bbox="188 1348 248 1409">A</td> <td data-bbox="248 1348 1115 1409">The carrying out of an anatomical examination</td> </tr> </table>		A
A	The carrying out of an anatomical examination	

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	
C	Storage of an anatomical specimen	
D	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	

If human tissue is stored under your establishment's licence, at either main site / hub or satellite sites, please indicate the scheduled purpose(s) for which the tissue may be used:	GUIDANCE Please tick all scheduled purposes that apply for the relevant material stored at your establishment
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	

Satellite sites:	GUIDANCE
* Number of satellite sites:	
<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, B, C, D (as above) • The details of Person Designated at each satellite site (Name and job title) 	<p>All sections marked with * cannot be left blank.</p> <p>Please number each satellite site.</p>

SELF ASSESSMENT AGAINST HTA STANDARDS: Anatomy

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	<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>* 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>		<p>Examples for C1:</p> <ul style="list-style-type: none"> • Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • Where applicable, there are agreements with third parties to ensure consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice.
<p>* C2 Information about the consent process is provided and in a variety of formats</p>		<p>Examples for C2:</p> <ul style="list-style-type: none"> • Standard operating procedures (SOPs) detail the procedure for providing information on consent • Independent interpreters are available when appropriate • Information is available in suitable formats
<p>* C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent</p>		<p>Examples for C3:</p> <ul style="list-style-type: none"> • Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained
<p>If any of the Consent standards are not applicable, please indicate which standard and why:</p>		

Governance and quality systems (GQS) standards

Standards	Self-rating	Guidance
<p>* GQS1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process</p>		<p>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 GQS1:</p> <ul style="list-style-type: none"> • Policies and procedures are in place, covering all licensable activities • Appropriate risk management systems are in place • Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes • Complaints system
<p>* GQS2 There is a documented system of quality management and audit</p>		<p>Examples for GQS2:</p> <ul style="list-style-type: none"> • A document control system, covering all documented policies and standard operating procedures (SOPs). • Schedule of audits • Change control mechanisms for the implementation of new operational procedures
<p>* GQS3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills</p>		<p>Examples for GQS3:</p> <ul style="list-style-type: none"> • Qualifications of staff and training are recorded, records showing attendance at training • Orientation and induction programmes • Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training • Training and reference manuals • Staff appraisal / review records and personal development plans are in place
<p>* GQS4 There is a systematic and planned approach to the management of records</p>		<p>Examples for GQS4:</p> <ul style="list-style-type: none"> • Documented procedures for the creation, amendment, retention and destruction of records • Regular audit of record content to check for completeness, legibility and accuracy • Back-up / recovery facility in the event of loss of records • Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

<p>* GQS5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail</p>		<p>Examples for GQS5:</p> <ul style="list-style-type: none"> • There is an identification system which assigns a unique code to each donation and to each of the products associated with it • An audit trail is maintained, which includes details of when and where the bodies / body parts were acquired, the uses to which the bodies / body parts were put, when the bodies / body parts were transferred and to whom
<p>* GQS6 There are systems to ensure that all adverse events are investigated promptly</p>		<p>Examples for GQS6:</p> <ul style="list-style-type: none"> • Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
<p>* GQS7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately</p>		<p>Examples for GQS7:</p> <ul style="list-style-type: none"> • 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 purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • Where appropriate, policies are in place to ensure that the premises are of a standard (and maintained to that standard) that ensures the dignity of deceased persons

		<ul style="list-style-type: none"> 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
* PFE2 Environmental controls are in place to avoid potential contamination		<p>Examples for PFE2:</p> <ul style="list-style-type: none"> Appropriate separation of relevant material Air classification system and maintenance of air quality, including control and monitoring of environmental conditions Documented cleaning and decontamination procedures Staff are provided with appropriate protective equipment and facilities that minimise risk of contamination
* PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.		<p>Examples for PFE3:</p> <ul style="list-style-type: none"> Relevant material, consumables and records are stored in suitable environments and precautions are taken to minimise risk of damage or theft and ensure the security of holdings Critical storage conditions are monitored and recorded System to deal with emergencies on 24 hour basis
* 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>Examples for PFE4:</p> <ul style="list-style-type: none"> Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation A system is in place to ensure that traceability of relevant material is maintained during transportation Records of transportation and delivery Records are kept of transfer agreements with recipients of relevant material Records are kept of any agreements with courier or transport companies
* PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored		<p>Examples for PFE5:</p> <ul style="list-style-type: none"> Records of calibration, validation and maintenance, including any agreements with maintenance companies Users have access to instructions for equipment and receive training in use and maintenance where appropriate Staff aware of how to report an equipment problem Contingency plan for equipment failure

If any of the PFE standards are not applicable, please indicate which standard and why	
--	--

Disposal standards

Standards	Self-rating	Guidance 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.
* D1 There is a clear and sensitive policy for disposing of human organs and tissue		Examples for D1: <ul style="list-style-type: none"> • Documented disposal policy • Policy is made available to the public • Compliance with health and safety recommendations
* D2 The reason for disposal and the methods used are carefully documented		Examples for D2: <ul style="list-style-type: none"> • Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal • Where applicable, disposal arrangements reflect specified wishes
If any of the Disposal standards are not applicable, please indicate which standard and why:		

ADDITIONAL QUESTIONS: Anatomy

<p>1. * Please describe the Designated Individual's role in governance and quality management systems</p> <div data-bbox="264 1289 1209 1356" style="border: 1px solid black; padding: 5px;"> <p>Takes the lead in management of governance and quality systems, with support from other members of staff</p> </div> <div data-bbox="264 1393 1209 1423" style="border: 1px solid black; padding: 5px;"> <p>Some involvement in management of governance and quality systems, in</p> </div>	<p>QUESTION GUIDANCE</p> <p>Please select one option for this question. All sections marked with * must be completed.</p>
--	---

<input type="text" value="addition to delegating responsibilities to other members of staff"/>	
<input type="text" value="Limited time to spend on governance and quality systems"/>	
<input type="text" value="No involvement in governance"/>	

2. * Have you had difficulties with staff retention over the past 12 months?

<input type="text" value="Yes"/>
<input type="text" value="No"/>

QUESTION GUIDANCE

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

3. * Are there ever any external people involved in licensable activities who are not either directly employed by your establishment or who are not students enrolled at your establishment?

<input type="text" value="External staff and / or students work at the establishment and follow their own procedures"/>
<input type="text" value="External staff and / or students work at the establishment and follow the establishment's procedures"/>
<input type="text" value="All staff and / or students are employed by / enrolled at the establishment"/>

QUESTION GUIDANCE

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

4. * Where do licensable activities take place at your establishment?

<input type="text" value="At a single location"/>
<input type="text" value="At separate locations, with Persons Designated named on the licence"/>

QUESTION GUIDANCE

Separate locations are considered as different rooms or departments within the same building and/or different buildings within the same licensed site. If your establishment has satellite sites then these are also considered to be separate locations.

Please select one option for this question.

At separate locations, with no staff named as Persons Designated on the licence	All sections marked with * must be completed.
---	---

<p>5. * Are storage locations appropriately secured?</p> <p>Yes</p> <p>No</p>	<p>QUESTION GUIDANCE</p> <p>Appropriately secured means that access to areas where licensable activities take place is limited to authorised persons only.</p> <p>Please select one option for this question.</p> <p>All sections marked with * must be completed.</p>
---	---

<p>6. * Do you store relevant material on behalf of another establishment?</p> <p>Yes, and all required agreements are in place</p> <p>Yes, but not all required agreements are in place</p> <p>No</p>	<p>QUESTION GUIDANCE</p> <p>Required agreements define the roles and responsibilities of all parties involved. Agreements should also specify any storage requirements that are necessary to maintain the integrity, security and traceability of the relevant material.</p> <p>Please select one option for this question.</p> <p>All sections marked with * must be completed.</p>
--	---

<p>7. * Do you loan or transfer relevant material to other locations?</p> <p>Yes, and all required agreements and documentation are in place</p> <p>Yes, but not all required agreements and documentation are in place</p> <p>No</p>	<p>QUESTION GUIDANCE</p> <p>Required agreements and documentation define the roles and responsibilities of all parties involved. Agreements should also specify any measures necessary to ensure that the integrity, security and traceability of the relevant material is maintained. Information on the transfer or loan of cadaveric material can be found in the code of practice on Anatomical examination (paragraphs 55-60).</p> <p><i>This link opens in a separate window:</i></p> <p>http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm</p>
---	---

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

8. * Typically how many embalmed bodies do you receive each year?

None
1 - 10
11 - 20
21 - 30
31 - 50
More than 50 (please specify how many below)

QUESTION GUIDANCE

Updated 10 May 2011

This question refers only to whole bodies which are received for use by your establishment and not to body parts. It includes bodies which are received embalmed and bodies which will be embalmed after receipt.

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

9. * If you receive embalmed bodies, do you receive sufficient numbers to meet your training needs?

Yes
No
We do not receive embalmed bodies

QUESTION GUIDANCE

Updated 10 May 2011

This question refers only to whole bodies which are received for use by your establishment and not to body parts. It includes bodies which are received embalmed and bodies which will be embalmed after receipt.

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

10. * If you receive parts from embalmed bodies, do you receive sufficient numbers to meet your training needs?

Yes
No
We do not receive parts from embalmed bodies

QUESTION GUIDANCE

This question refers to embalmed body parts only and not whole bodies or fresh frozen body parts.

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

<p>11. What type of relevant material do you use / store?</p> <table border="1"> <tr><td>Bones / skeletons</td></tr> <tr><td>Potted specimens</td></tr> <tr><td>Plastinated specimens</td></tr> <tr><td>Frozen tissue</td></tr> <tr><td>Embalmed bodies or body parts</td></tr> <tr><td>Fetal specimens</td></tr> <tr><td>Specimens from children</td></tr> <tr><td>Blocks and slides</td></tr> </table>	Bones / skeletons	Potted specimens	Plastinated specimens	Frozen tissue	Embalmed bodies or body parts	Fetal specimens	Specimens from children	Blocks and slides	<p style="text-align: center;">QUESTION GUIDANCE</p> <p style="text-align: center;">Please tick all that are applicable.</p>
Bones / skeletons									
Potted specimens									
Plastinated specimens									
Frozen tissue									
Embalmed bodies or body parts									
Fetal specimens									
Specimens from children									
Blocks and slides									
<p>12. * Do you store plastinated material?</p> <table border="1"> <tr><td>Yes</td></tr> <tr><td>No</td></tr> <tr><td>We do not store plastinated material</td></tr> </table>	Yes	No	We do not store plastinated material	<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>					
Yes									
No									
We do not store plastinated material									
<p>13. * In the past two years, have you purchased fresh frozen material to enable healthcare professionals to rehearse medical or surgical procedures?</p> <table border="1"> <tr><td>Yes</td></tr> <tr><td>Yes, and we are likely to increase our activity in this area</td></tr> <tr><td>No</td></tr> </table>	Yes	Yes, and we are likely to increase our activity in this area	No	<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>					
Yes									
Yes, and we are likely to increase our activity in this area									
No									
<p>14. * If you use or store fresh frozen material, do you:</p> <table border="1"> <tr><td>Thaw it only once and dispose after use</td></tr> <tr><td>Thaw and refreeze the material for several uses before it is disposed of</td></tr> <tr><td>We do not use or store fresh frozen material</td></tr> </table>	Thaw it only once and dispose after use	Thaw and refreeze the material for several uses before it is disposed of	We do not use or store fresh frozen material	<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>					
Thaw it only once and dispose after use									
Thaw and refreeze the material for several uses before it is disposed of									
We do not use or store fresh frozen material									

15. * If fresh frozen material is used, is testing for infectious diseases carried out in line with the requirements of the HTA 'Policy on the import of fresh frozen bodies and body parts' (HTA-POL-043)?

Yes

No

We do not use or store fresh frozen material

QUESTION GUIDANCE

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

The Policy is available from the HTA website.
This link opens in a separate window:

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/policyontheimportoffreshfrozenbodiesandbodyparts.cfm>

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)