

Reference document – Research 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 Research 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 Post Mortem).
- 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: Research

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 licensed under:	Please select your sector. This will ensure you are completing the correct form for your establishment. All sections marked with * must be completed.

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> <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:		
Your contact details:			
* 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> <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:		

Named persons working under the licence:	<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;">Please complete this section for your main site / hub (if there are satellite sites).</p> <p style="text-align: center;">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>	

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

Please confirm the licensable activities being undertaken at your establishment:		<p style="text-align: center;">GUIDANCE</p>
A	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	

<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>* Number of satellite sites:</p>	
<p>For each satellite site, please provide the following details:</p>	

- Satellite name and address
- The licensable activities carried out at each satellite site (indicate A)
- The details of Person Designated at each satellite site (Name and job title)

See section above for licensable activities.

SELF ASSESSMENT AGAINST HTA STANDARDS: Research

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

SELF ASSESSMENT AGAINST HTA STANDARDS: Research

Consent standards

Standards	Self-rating	Guidance
		<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>* 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 • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
<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) details the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation • Consent procedures have been ethically approved
<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>Examples for GQS1:</p> <ul style="list-style-type: none"> • Policies and procedures in place are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body • 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 There are documented procedures for distribution of body parts, tissues or cells</p>		<p>Examples for GQS5:</p> <ul style="list-style-type: none"> • A process is in place to review the release of relevant material to other organisations • An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return
<p>* GQS6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail</p>		<p>Examples for GQS6:</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 relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom
<p>* GQS7 There are systems to ensure that all adverse events are investigated promptly</p>		<p>Examples for GQS7:</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>* GQS8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately</p>		<p>Examples for GQS8:</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

If any of the GQS standards are not applicable, please indicate which standard and why:	
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Premises, facilities and equipment (PFE) 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>
* PFE1 The premises are fit for purpose		<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 • 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"> • Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • Appropriate health and safety controls are in place
* 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 secure environments and precautions are taken to minimise risk of damage, theft or contamination • Contingency plans are in place in case of failure in storage area • Critical storage conditions are monitored and recorded

		<ul style="list-style-type: none"> • System to deal with emergencies on 24 hour basis • Records indicating where the material is stored in the premises
* 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 transport • Records of transportation and delivery • Records are kept of any 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
		<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>* 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"> • Documented disposal policy • Policy is made available to the public • 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"> • 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
<p>If any of the Disposal standards are not applicable, please indicate which standard and why:</p>		

ADDITIONAL QUESTIONS: Research

<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</p>	<p style="text-align: center;">QUESTION GUIDANCE</p> <p style="text-align: center;">Please select one option for this question.</p> <p style="text-align: center;">All sections marked with * must be completed.</p>
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<p>2. * Do you have any difficulties currently in recruiting or retaining staff?</p> <table border="1" data-bbox="248 304 472 443"> <tr> <td data-bbox="248 304 472 376">Yes</td> </tr> <tr> <td data-bbox="248 376 472 443">No</td> </tr> </table>	Yes	No	<p style="text-align: center;">QUESTION GUIDANCE</p> <p style="text-align: center;">Please select one option for this question.</p> <p style="text-align: center;">All sections marked with * must be completed.</p>
Yes			
No			

<p>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?</p> <table border="1" data-bbox="248 667 1227 951"> <tr> <td data-bbox="248 667 1227 775">External staff and / or students work at the establishment and follow their own procedures</td> </tr> <tr> <td data-bbox="248 775 1227 884">External staff and / or students work at the establishment and follow the establishment's procedures</td> </tr> <tr> <td data-bbox="248 884 1227 951">All staff and / or students are employed by / enrolled at the establishment</td> </tr> </table>	External staff and / or students work at the establishment and follow their own procedures	External staff and / or students work at the establishment and follow the establishment's procedures	All staff and / or students are employed by / enrolled at the establishment	<p style="text-align: center;">QUESTION GUIDANCE</p> <p style="text-align: center;">Please select one option for this question.</p> <p style="text-align: center;">All sections marked with * must be completed.</p>
External staff and / or students work at the establishment and follow their own procedures				
External staff and / or students work at the establishment and follow the establishment's procedures				
All staff and / or students are employed by / enrolled at the establishment				

<p>4. * Where is relevant material stored at your establishment?</p> <table border="1" data-bbox="248 1086 1223 1203"> <tr> <td data-bbox="248 1086 1223 1129">At a single location</td> </tr> <tr> <td data-bbox="248 1129 1223 1173">At separate locations, with Persons Designated named on the licence</td> </tr> <tr> <td data-bbox="248 1173 1223 1203">At separate locations, with no staff named as Persons Designated on the licence</td> </tr> </table>	At a single location	At separate locations, with Persons Designated named on the licence	At separate locations, with no staff named as Persons Designated on the licence	<p style="text-align: center;">QUESTION GUIDANCE</p> <p>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.</p> <p style="text-align: center;">Please select one option for this question.</p> <p style="text-align: center;">All sections marked with * must be completed.</p>
At a single location				
At separate locations, with Persons Designated named on the licence				
At separate locations, with no staff named as Persons Designated on the licence				

<p>5. * Are storage locations appropriately secured?</p> <table border="1" data-bbox="248 336 409 477"> <tr> <td>Yes</td> </tr> <tr> <td>No</td> </tr> </table>	Yes	No	<p style="text-align: center;">QUESTION GUIDANCE</p> <p>Appropriately secured means that access to areas where licensable activities take place is limited to authorised persons only.</p> <p style="text-align: center;">Please select one option for this question.</p> <p style="text-align: center;">All sections marked with * must be completed.</p>
Yes			
No			

<p>6. * Do you store relevant material on behalf of another establishment?</p> <table border="1" data-bbox="248 676 1133 884"> <tr> <td>Yes, and all required agreements are in place</td> </tr> <tr> <td>Yes, but not all required agreements are in place</td> </tr> <tr> <td>No</td> </tr> </table>	Yes, and all required agreements are in place	Yes, but not all required agreements are in place	No	<p style="text-align: center;">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 style="text-align: center;">Please select one option for this question.</p> <p style="text-align: center;">All sections marked with * must be completed.</p>
Yes, and all required agreements are in place				
Yes, but not all required agreements are in place				
No				

<p>7. * Do you transfer relevant material to other locations?</p> <table border="1" data-bbox="248 1099 1240 1308"> <tr> <td>Yes, and all required agreements and documentation are in place</td> </tr> <tr> <td>Yes, but not all required agreements and documentation are in place</td> </tr> <tr> <td>No</td> </tr> </table>	Yes, and all required agreements and documentation are in place	Yes, but not all required agreements and documentation are in place	No	<p style="text-align: center;">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.</p> <p style="text-align: center;">Please select one option for this question.</p> <p style="text-align: center;">All sections marked with * must be completed.</p>
Yes, and all required agreements and documentation are in place				
Yes, but not all required agreements and documentation are in place				
No				

<p>8. * Is your establishment, or does it contain, a tissue bank?</p> <table border="1"> <tr> <td data-bbox="248 272 1095 443">Yes, and all tissue banks have generic ethical approval for a research tissue bank from an NHS research ethics committee</td> </tr> <tr> <td data-bbox="248 443 1095 614">Yes, but not all tissue banks have generic ethical approval for a research tissue bank from an NHS research ethics committee</td> </tr> <tr> <td data-bbox="248 614 1095 715">Yes, but none of our tissue banks have generic ethical approval for a research tissue bank from an NHS research ethics committee</td> </tr> <tr> <td data-bbox="248 715 1095 788">No</td> </tr> </table>	Yes, and all tissue banks have generic ethical approval for a research tissue bank from an NHS research ethics committee	Yes, but not all tissue banks have generic ethical approval for a research tissue bank from an NHS research ethics committee	Yes, but none of our tissue banks have generic ethical approval for a research tissue bank from an NHS research ethics committee	No	<p style="text-align: center;">QUESTION GUIDANCE</p> <p>Generic ethical approval is explained further in our code of practice on Research, paragraphs 68 - 71</p> <p style="text-align: center;"><i>This link opens in a separate window:</i></p> <p style="text-align: center;">http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm</p> <p style="text-align: center;">Please select one option for this question.</p> <p style="text-align: center;">All sections marked with * must be completed.</p>
Yes, and all tissue banks have generic ethical approval for a research tissue bank from an NHS research ethics committee					
Yes, but not all tissue banks have generic ethical approval for a research tissue bank from an NHS research ethics committee					
Yes, but none of our tissue banks have generic ethical approval for a research tissue bank from an NHS research ethics committee					
No					

<p>9. * Which of the following terms best describes your establishment:</p> <table border="1"> <tr> <td data-bbox="248 935 1223 1007">Commercial</td> </tr> <tr> <td data-bbox="248 1007 1223 1078">Academic</td> </tr> <tr> <td data-bbox="248 1078 1223 1150">NHS</td> </tr> <tr> <td data-bbox="248 1150 1223 1222">Charity</td> </tr> <tr> <td data-bbox="248 1222 1223 1294">Other (please specify below)</td> </tr> </table>	Commercial	Academic	NHS	Charity	Other (please specify below)	<p style="text-align: center;">QUESTION GUIDANCE</p> <p style="text-align: center;">Please select one option for this question.</p> <p style="text-align: center;">All sections marked with * must be completed.</p> <p style="text-align: center;">If 'other' has been selected, please provide a description of your establishment and the activities which are carried out in the space provided.</p>
Commercial						
Academic						
NHS						
Charity						
Other (please specify below)						

10. * How many relevant material samples do you store?

Less than 100

100 - 500

501 - 1000

More than 1000 (please specify below)

QUESTION GUIDANCE

The number of samples includes all individual items of relevant material held under the licence, including any aliquots or parts of the original sample. Further guidance on what constitutes relevant material can be found on the HTA website.

This link opens in a separate window:

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

Please select one option for this question.

All sections marked with * must be completed.

11. Do you store any of the following types of relevant material?

Specimens from the deceased

Specimens from children

Fetal specimens

Brains

Hearts

QUESTION GUIDANCE

Please tick all that are applicable.

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)