Post Mortem Licence Application

If you carry out post mortem examinations, or store or remove post mortem material, you can apply for a licence using this application form.

Guidance on completing this form and further information about licensing is available on the HTA website.

Click here for further information about the role and responsibilities of Designated Individuals and Licence Holders under the Human Tissue Act.

Establishment Information

A licence application must specify the premises where the activities are to take place; this should be the address of the main site. Where the licensed activity will take place at more than one premises (i.e. a main site with remote satellite sites), a separate satellite licence will be needed for each site.

Name of establishment to be licensed	
Address of establishment to be licensed	Postcode:
Are you applying to replace an existing Human Tissue Authority licence?	Yes ☐ No ☐ If yes, please state the licence number you are applying to replace. Existing licence number:
Activities to be licensed	☐ Section 16(2)(b) - The making of a post mortem examination ☐ Section 16(2)(c) – The removal from the body of a deceased person of relevant material of which the body consists or which it contains for use of a Scheduled Purpose other than transplantation (where removal is not in the course of a post mortem examination) ☐ Section 16(2)(e)(i) and (ii) – 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.
What relevant material will be stored under the licence?	
What types of procedures take place at the establishment? Please provide annual numbers for post mortems.	**Adult** ☐ Coroner's post mortem examinations Number: ☐ Forensic post mortem examinations Number: ☐ Hospital post mortem examinations Number: **Paediatric** ☐ Coroner's post mortem examinations Number: ☐ Forensic post mortem examinations Number:

	☐ Hospital post mortem examinations Number: **General** ☐ Storage of bodies ☐ Storage of body parts ☐ Removal of relevant material ☐ Consent ☐ Other – please describe:
How many staff members are involved in carrying out the licensable activity/ies at the main site?	
What organisations or private individuals, if any, are you holding samples on behalf of?	
Do you supply or use tissue for research purposes?	Yes ☐ No ☐
To assist the Human Tissue Authority, please provide a synopsis describing: • The activities taking place • How long the activities have been taking place • How the facility is used • How the facility relates or interacts with other establishments	
How many adverse incidents have occurred in the establishment in the past 12 months?	
Please provide names of the proposed Persons Designated for the licence if the establishment is applying for a licence on one premises	

Establishment Accreditations

Does the establishment have any form of professional accreditation? (Such as CPA)	Yes ☐ No ☐ If yes, please complete the questions below for each accreditation. Please continue on separate sheets if necessary.

Accrediting body:

Date accredited: DD/MM/YYYY Date enrolled: DD/MM/YYYY

Awaiting assessment? Yes ☐ No ☐ Conditional approval date: DD/MM/YYYY

Any further information, such as explanation of the activities covered by the accreditations:

Accrediting body:

Date accredited: DD/MM/YYYY Date enrolled: DD/MM/YYYY

Awaiting assessment? Yes ☐ No ☐ Conditional approval date: DD/MM/YYYY

Any further information, such as explanation of the activities covered by the accreditations:

Accrediting body:

Date accredited: DD/MM/YYYY Date enrolled: DD/MM/YYYY

Awaiting assessment? Yes ☐ No ☐ Conditional approval date: DD/MM/YYYY

Any further information, such as explanation of the activities covered by the accreditations:

Accrediting body:

Date accredited: DD/MM/YYYY Date enrolled: DD/MM/YYYY

Awaiting assessment? Yes ☐ No ☐ Conditional approval date: DD/MM/YYYY

Any further information, such as explanation of the activities covered by the accreditations:

Satellite Sites

To be completed by the Designated Individual

Does the establishment have any satellite sites? Yes ☐ No ☐

If yes, please complete the below information for each satellite site. If you have more than two satellite sites you can copy and paste this part of the form onto a separate sheet.

Satellite 1

Name:
Address:

Postcode:

Activities undertaken at satellite:

☐ Section 16(2)(b) - The making of a post mortem examination

☐ Section 16(2)(c) – The removal from the body of a deceased person of relevant material of which the body consists or which it contains for use of a Scheduled Purpose other than transplantation (where removal is not in the course of a post mortem examination)

☐ Section 16(2)(e)(i) and (ii) – The storage of the body of a deceased person or relevant material which has come from a human body for use for a Scheduled Purpose

Person(s) Designated at the site	**Job title**	**Email address**	**Telephone number**
Primary:			
Additional:			
Additional:			

When did the site become operational? (approximate date)	
Please explain how the satellite site links to the governance of the hub	
To assist the Human Tissue Authority, please provide a short synopsis describing how the facility is used	
Please explain what responsibilities the staff at the satellite site have for meeting the consent	

requirements of the Human Tissue Act and Codes of Practice	
Does the satellite store relevant material on behalf of any organisation other than the hub?	Yes ☐ No ☐ If yes, please provide details.
Does the satellite supply or use relevant material for research purposes?	Yes ☐ No ☐
Please state how many adverse events have occurred at the satellite in the last year	
Does the satellite have any form of accreditation, such as CPA, MHRA, JACIE, ISO etc?	Yes ☐ No ☐ If yes, please provide the following information for each accreditation: Accrediting body: Date accreditation obtained: Current status:
Please provide any relevant further information	

Name of person who completed this form (must be either the DI or LH from the hub):	Date: DD/MM/YYYY

Satellite 2
Name:
Address:

Postcode:

Activities undertaken at satellite:
☐ Section 16(2)(b) - The making of a post mortem examination

☐ Section 16(2)(c) – The removal from the body of a deceased person of relevant material of which the body consists or which it contains for use of a Scheduled Purpose other than transplantation (where removal is not in the course of a post mortem examination)

☐ Section 16(2)(e)(i) and (ii) – The storage of the body of a deceased person or relevant material which has come from a human body for use for a Scheduled Purpose

Person(s) Designated at the site	**Job title**	**Email address**	**Telephone number**
Primary:			
Additional:			
Additional:			

When did the site become operational? (approximate date)	
Please explain how the satellite site links to the governance of the hub	
To assist the Human Tissue Authority, please provide a short synopsis describing how the facility is used	
Please explain what responsibilities the staff at the satellite site have for meeting the consent requirements of the Human Tissue Act and Codes of Practice	
Does the satellite store relevant material on behalf of any organisation other than the hub?	Yes ☐ No ☐ If yes, please provide details.
Does the satellite supply or use relevant material for research purposes?	Yes ☐ No ☐
Please state how many adverse events have occurred at the satellite in the last year	
Does the satellite have any form of accreditation, such as CPA, MHRA, JACIE, ISO etc?	Yes ☐ No ☐ If yes, please provide the following information for each accreditation: Accrediting body: Date accreditation obtained: Current status:

Please provide any relevant further information		
Name of person who completed this form (must be either the DI or LH from the hub):		Date: DD/MM/YYYY

Application to be Designated Individual (DI)

To be completed by proposed DI.

Title	
Forenames	
Surname	
If you have been known by another name, please provide details	
Correspondence address	Postcode:
Email	
Telephone	
Fax	
Job title	
Have you ever applied to be a DI for another establishment?	Yes ☐ No ☐ If yes, please provide the establishment name and the application reference number.
Educational and/or professional qualifications	
Membership of relevant professional bodies and registration numbers where applicable	
Details of any other relevant experience, including managerial experience and training	
With regard to the organisational structure of the establishment, please indicate the lines of responsibility between the DI and any persons working under the licence	
Please explain your involvement in ensuring that staff who will work under the licence are	

appropriately qualified and trained in techniques relevant to their work and that they are continuously updating their skills	
Please explain your involvement in governance and quality management activities within the establishment	
Please explain why you think you are suitable for the role of DI	

Declaration by proposed Designated Individual

Any person making an application and submitting a compliance report should be aware that under paragraph 7(2)(a) of Schedule 3 of the Human Tissue Act 2004, the Human Tissue Authority may revoke a licence if it is satisfied that any information given for the purposes of the application for a licence was in any material respect false and misleading.

I understand the terms and conditions under which a licence will be granted under the Human Tissue Act 2004, particularly my duties under Section 18 of the HT Act and confirm:

a) I will follow the guidance set out in the Codes of Practice produced by the Human Tissue Authority and as amended from time to time. Yes ☐ No ☐

b) The licensed activities will be carried out under my supervision. Yes ☐ No ☐

c) I accept I am responsible for securing that the other persons to whom the licences apply are suitable persons to participate in the carrying out of the licensed activities. Yes ☐ No ☐

d) I accept that I am responsible for securing that suitable practises are used by the persons under my supervision in the course of carrying out the licensed activities. Yes ☐ No ☐

e) I accept I am responsible for compliance with the conditions of any licences granted. Yes ☐ No ☐

f) The information provided is true and accurate to the best of my knowledge. Yes ☐ No ☐

g) I consent to be the Designated Individual for the licence(s). Yes ☐ No ☐

Name: Date: DD/MM/YYYY

Application to be Individual Licence Holder (LH)

(if different from DI)

This section is to be completed when an individual person is applying to be the LH. If a corporate body is applying to be the LH please move on to the next section.

Title	
Forenames	
Surname	
If you have been known by another name, please provide details	
Correspondence address	Postcode:
Email	
Telephone	
Fax	
Job title	
Educational and/or professional qualifications	
Membership of relevant professional bodies and registration numbers where applicable	
Details of any other relevant experience, including managerial experience and training	
Please explain why you think you are suitable for the role of the LH	

Declaration by proposed Licence Holder

Any person making an application should be aware that under paragraph 7(2)(d) and (g) of Schedule 3 of the Human Tissue Act 2004, the Human Tissue Authority may revoke a licence if it:
(a) ceases to be satisfied that the person to whom the licence is granted is a suitable person to be the holder of the licence, and
(b) is satisfied that there has been a material change of circumstances since the licence was granted.

I understand the terms and conditions under which a licence is granted and varied under the Human Tissue Act 2004 and confirm:

a) The information provided is true and accurate.	Yes ☐	No ☐
b) The Designated Individual has consented to this application.	Yes ☐	No ☐
Name:	Date: DD/MM/YYYY	

Application to be Corporate Licence Holder (LH)

This section is to be completed when a corporate body is applying to be the LH. If an individual person is applying to be the LH please complete the previous section instead.

Details of person completing this form on behalf of the proposed Corporate Licence Holder:	
Title	
Forename	
Surname	
If you have been known by another name, please give details	
Email	
Telephone	
Fax	
Job title	
Name and job title of person authorised to sign on behalf of the corporate body	Name: Job title:
Full name of corporate body	
Trading name or business name if different from company name	
Type of corporate body and relevant details	☐ Limited company Company registration number: ☐ Sole proprietor Name and address: ☐ Public Limited Company Company registration number: ☐ Charity Charity registration number: ☐ Partnership Names and addresses of partners: ☐ NHS Organisation Please describe: ☐ Other public body Please describe:

	☐ Higher Education Institution ☐ Other Please describe:
Name and registered office of parent company, if applicable	
If the body has been known by another name in the past five years please provide details	
Please explain why the corporate body is suitable for the role of the Corporate Licence Holder	

Declaration by proposed Corporate Licence Holder

Any person making an application should be aware that under paragraph 7(2)(d) and (g) of Schedule 3 of the Human Tissue Act 2004, the Human Tissue Authority may revoke a licence if it:
(a) ceases to be satisfied that the person to whom the licence is granted is a suitable person to be the holder of the licence, and
(b) is satisfied there has been a material change of circumstances since the licence was granted.

I understand the terms and conditions under which a licence is granted and varied under the Human Tissue Act 2004 and confirm:

a) The information provided is true and accurate. Yes ☐ No ☐

b) The Designated Individual has consented to this application. Yes ☐ No ☐

c) I have been authorised to make this application on behalf of the applicant corporate body. Yes ☐ No ☐

Name: Date: DD/MM/YYYY

Human Tissue Authority Standards

Consent

C1	Consent is obtained in accordance with the requirements of the HT Act 2004 and as set out in the Codes of Practice.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
C2	Information about the consent process is provided and in a variety of formats.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
C3	Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		

Governance and Quality Systems

GQ1	All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
GQ2	There is a documented system of quality management and audit.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
GQ3	Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	☐ Not applicable ☐ Not met ☐ Partially met

		☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
GQ4	There is a systematic and planned approach to the management of records.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
GQ5	There are documented procedures for donor selection and exclusion, including donor criteria.	☒ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
You do not need to provide a response to this Standard as it is not relevant to the Post Mortem sector.		
GQ6	A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
GQ7	There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
GQ8	Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		

Premises, Facilities and Equipment		
PFE1	The premises are fit for purpose.	☐ Not applicable ☐ Not met

		☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
PFE2	Environmental controls are in place to avoid potential contamination.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
PFE3	There are appropriate facilities for the storage of bodies, body parts, tissues and cells.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
PFE4	Systems are in place to protect the quality and integrity of bodies and body parts during transport and delivery to a destination.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
PFE5	Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		

Disposal		
D1	There is a clear and sensitive policy for disposing of human organs and tissue.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
D2	Post Mortem tissue is disposed of if consent is not given	☐ Not applicable

for its storage and use for scheduled purposes.	☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.	

Please return this application form by email to licensing.enquiries@hta.gov.uk.