

# Pathology

## Compliance Report

If you carry out post mortem examinations, or store or remove post mortem material, you can apply for a licence from July 2006, using the online Compliance Report on the Human Tissue Authority (HTA) website [www.hta.gov.uk](http://www.hta.gov.uk)

Please do not complete and submit this form – it is provided for reference only, to help you prepare answers to the questions.

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

## Application to be Designated Individual (DI)

Title

Forenames

Surname

If you have been known  
by another name, please  
give details

Date of birth

Email

Telephone

Fax

Job title

Employer

Establishment's name

Address of premises  
where licensed activities  
are to take place

Postcode

- Activities to be licensed
- The making of a post-mortem examination
  - The removal from the body of a deceased person (otherwise than in the course of carrying out an anatomical examination or making a post mortem) of relevant material of which the body consists or which it contains, for use for a Scheduled Purpose other than transplantation
  - 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

Have you applied to be a DI for another establishment? If so, please give:

Application reference number

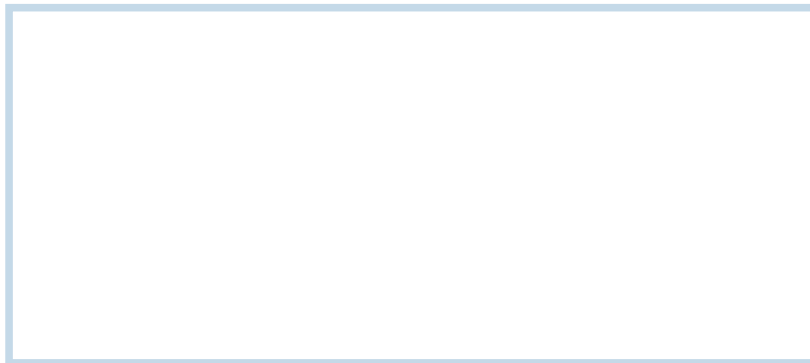
Establishment name

Educational or professional qualifications

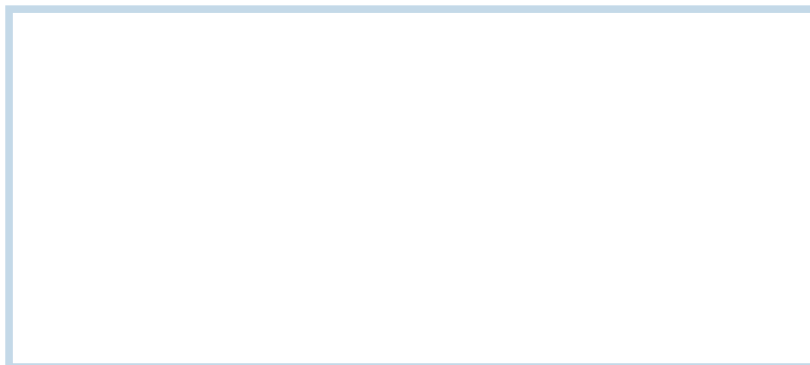
Membership of relevant professional bodies (please provide registration numbers where applicable)

Details of any other relevant experience including managerial experience and training

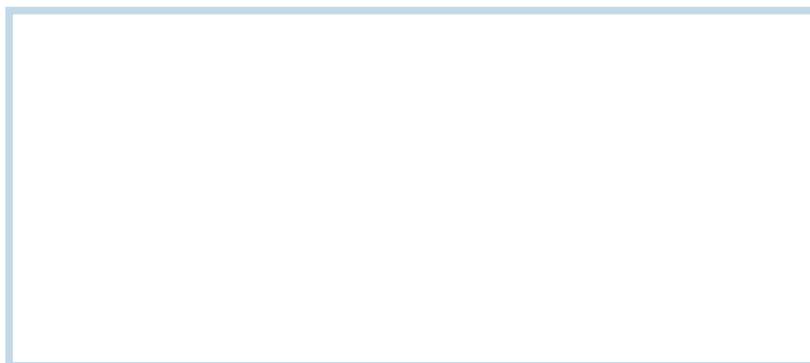
With regard to the organisational structure of the establishment, please indicate the lines of responsibility between the DI and any persons working under the licence



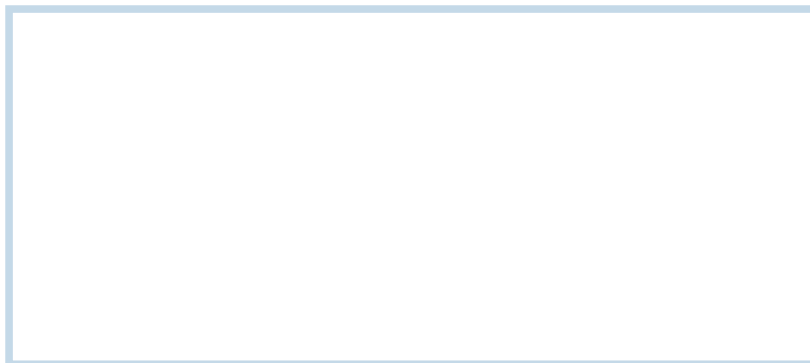
Please explain your involvement in ensuring that staff who will work under the licence are appropriately qualified and trained in techniques relevant to their work and that they are continuously updating their skills



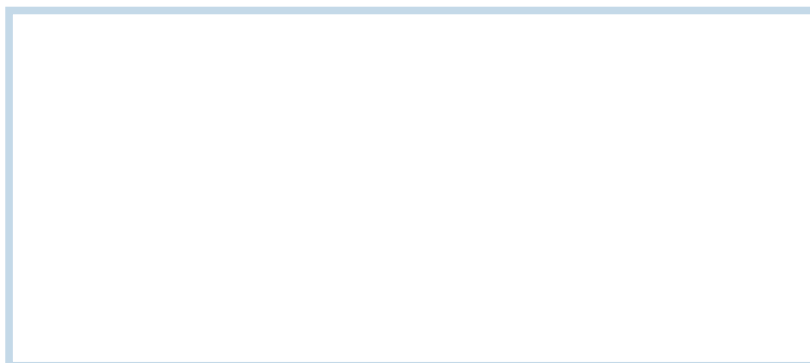
Please explain your involvement in governance and quality management activities within the establishment



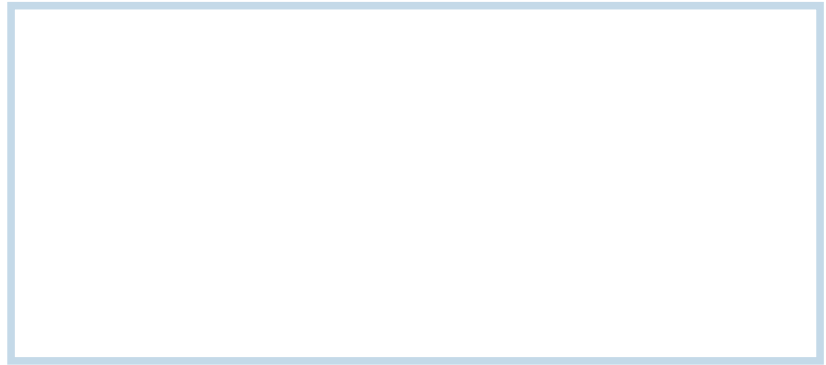
Please explain why you think you are suitable for the role of DI



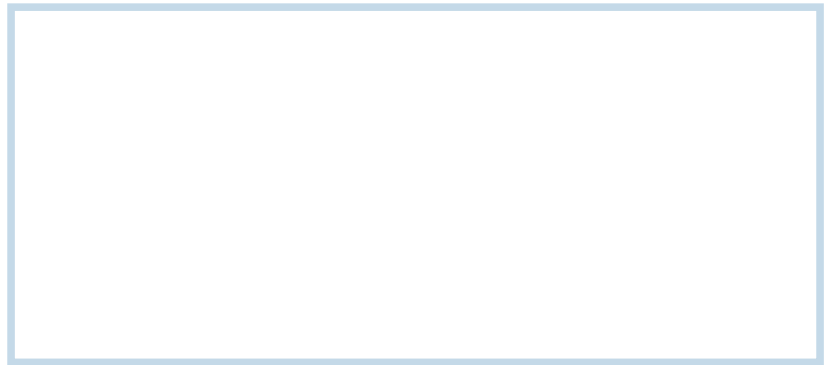
Names of person(s) who have consented to be designated on the licence (where establishment is applying for a licence(s) on one premises)



Address(es) of satellite site's premises and activities to be licensed

A large, empty rectangular box with a light blue border, intended for providing the address(es) of the satellite site's premises and activities to be licensed.

Names of person(s) who have consented to be designated on the licence at the satellite premises

A large, empty rectangular box with a light blue border, intended for providing the names of person(s) who have consented to be designated on the licence at the satellite premises.

## Declaration by proposed DI

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 (HT Act), the Human Tissue Authority (HTA) 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 HT 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 HTA 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 DI for the licence application made by the proposed licence holder and where applicable consent to be the licence holder.  Yes  No

Date

## Application to be Licence Holder (If different from DI)

Title

Forenames

Surname

If you have been known  
by another name, please  
give details

Date of birth

D	D	M	M	Y	Y	Y	Y
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Email

Telephone

Fax

Job title

Employer

Educational or professional  
qualifications

Membership of relevant professional and / or statutory bodies (please provide registration numbers where applicable)

Details of any other relevant professional experience including managerial experience and training

Please state why you think you are suitable to be the Licence Holder

## Declaration by the applicant

Any person making an application and submitting a compliance report should be aware that under paragraph 7(2)(a) of Schedule 3 of the HT Act 2004, the HTA 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 HT Act 2004, and confirm

- a) The information provided is true and accurate  Yes  No
- b) The DI has consented to this application  Yes  No

Date

D	D	M	M	Y	Y	Y	Y
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## Application to be a Corporate Licence Holder

Full name of body

Trading name / business name  
if different from company name

Type of corporate body

- Limited Company
- Sole Proprietor
- Public Limited Company
- Partnership
- Charity
- NHS Organisation
- Other Public Body, please describe

- Higher Education Institution
- Other, please describe

**Please provide:**

*If a Private / Public / Limited Company*  
Co. Registered No.

*If a sole proprietor*  
Name and address

*If a charity*  
Charities Registered No.

*If partnership*  
Names and addresses of partners

*Other*  
Trading / Business Address

Name and registered office of  
parent company, if any

If the body has been known by  
another name in the past five  
years please give details

Year when established

Name of person completing this application on behalf of the corporate body

Email

Telephone

Fax

Please explain why the corporate body is suitable for the role of Licence Holder

## Declaration by the corporate applicant

Any person completing this application and compliance report should be aware that under paragraph 7(2)(a) of Schedule 3 of the HT Act 2004, the HTA 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

On behalf of the corporate body I accept the terms and conditions under which a licence will be granted under the HT Act 2004, and confirm

- a) The information provided is true and accurate  Yes  No
- b) The DI has consented to this application  Yes  No
- c) I have been authorised to make this application on behalf of the applicant  Yes  No

Date

## Establishment information

Parent organisation if applicable  
(e.g. NHS Trust)

What will be stored under  
the licence?

What types of procedures take  
place at the establishment?

- Coroner's post mortems
- Hospital post mortems
- Storage of bodies
- Storage of body parts
- Donor selection
- Removal of material
- Consent
- Other

What organisations if any, are you  
holding samples on behalf of?

Do you supply or use tissue  
for research purposes?

To assist the HTA, please provide a short synopsis describing your establishment

Please document how many adverse events have occurred in your establishment in the past 12 months

## Information about inspection and accreditation

Does the establishment have any form of professional accreditation, for example CPA?

Yes  No

If YES give the date of the accreditation and some information about the activities covered by the accreditation / licence:

Accredited CPA

Date

D	D	M	M	Y	Y	Y	Y
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Further information:

Enrolled

Date

Awaiting assessment

Conditional approval

Date

Does the establishment have any other form of accreditation?

Yes  No

If YES give the date of the accreditation and some information about the activities covered by the accreditation / licence:

Accredited Medicines and  
Healthcare products Regulatory  
Authority (MHRA)

Date

Accredited ISO / 9000

Date

Accredited Investors in People

Date

Further information:  
(e.g. explaining the activities  
covered by the accreditation)

## Consent

**C1** Consent is obtained in accordance with the requirements of the HT Act 2004 and as set out in the Code of Practice.

Self-assessment rating			
1	2	3	4

Please provide examples

*Examples of evidence of compliance*

- *Consent forms comply with the HTA Code of Practice*
- *Consent forms are in records and are made accessible to those using or releasing bodies, body parts or tissue for a Scheduled Purpose*
- *If third parties act as procurers, Service Level Agreements require third parties to ensure that consent is obtained in accordance with the requirements of the Human Tissue Act 2004 and the HTA's Code of Practice*
- *If the establishment acts as a procurer an effective and reliable process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Code of Practice*

HTA rating			
1	2	3	4

**C2** Information about the consent process is provided and in a variety of formats.

Self-assessment rating			
1	2	3	4

Please provide examples

*Examples of evidence of compliance*

- *Standard Operating Procedures detailing the procedure for providing information on consent*
- *Service Level Agreements contain appropriate information*
- *Availability of independent interpreters when appropriate*
- *Information available in suitable formats*

HTA rating			
1	2	3	4

**C3** Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.

Self-assessment rating			
1	2	3	4

Please provide examples

*Examples of evidence of compliance*

- *Standard Operating Procedures detailing the consent process*
- *Evidence of suitable training of staff involved in seeking consent*
- *Records demonstrate up to date staff training*
- *Staff and user feedback*

HTA rating			
1	2	3	4

Estimated time to complete  
20 minutes

Actual time to complete

## 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.

Self-assessment rating			
1	2	3	4

Please provide examples

HTA rating			
1	2	3	4

*Examples of evidence of compliance*

- *Policies and procedures in place covering all licensable activities*
- *Appropriate risk management systems*
- *Regular governance meetings for example health and safety and risk management committees agendas and minutes*
- *Complaints system*

**GQ2** There is a documented system of quality management and audit.

Self-assessment rating			
1	2	3	4

Please provide examples

*Examples of evidence of compliance*

- *A document control system covering all documented policies and standard operating procedures.*
- *Schedule of internal / quality audits*
- *Change control mechanisms to ensure implementation of new operational procedures*

HTA rating			
1	2	3	4

**GQ3** Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.

Self-assessment rating			
1	2	3	4

Please provide examples

*Examples of evidence of compliance*

- *Qualifications of staff and training records showing attendance at training*
- *Orientation and induction programmes*
- *Documented training programme (e.g. health and safety, fire, risk management, infection control) and developmental training*
- *Training and reference manuals*
- *Staff appraisal records and personal development plans*

HTA rating			
1	2	3	4

**GQ4** There is a systematic and planned approach to the management of records.

Self-assessment rating			
1	2	3	4

Please provide examples

*Examples of evidence of compliance*

- *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 computerised records*
- *Systems ensure data protection and confidentiality and public disclosure (whistleblowing)*

HTA rating			
1	2	3	4

**GQ5** There are documented procedures for donor selection and exclusion, including donor criteria.

Self-assessment rating			
1	2	3	4

Please provide examples

*Examples of evidence of compliance*

- *Suitability criteria are established to ensure that donor evaluation and selection is carried out in line with statutory requirements*
- *Records of medical and behavioural history and microbiological screening are in evidence*

HTA rating			
1	2	3	4

**GQ6** A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.

Self-assessment rating			
1	2	3	4

Please provide examples

*Examples of evidence of compliance*

- *There is a donor 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 the body, body parts, tissues or cells were acquired and where from; the uses to which the body, body parts, tissues or cells were put; when the body, body parts, tissues or cells were transferred elsewhere and to whom*

HTA rating			
1	2	3	4

**GQ7** There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.

Self-assessment rating			
1	2	3	4

Please provide examples

*Examples of evidence of compliance*

- *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. NPSA Alerts, HTA Communications)*

HTA rating			
1	2	3	4

**GQ8** Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.

Self-assessment rating			
1	2	3	4

Please provide examples

HTA rating			
1	2	3	4

*Examples of evidence of compliance*

- *Documented risk assessments for all practices and processes*
- *Risk assessments are reviewed when appropriate i.e. minimum annually or if anything changes*
- *Staff can access risk assessments and are made aware of local hazards at training*

Estimated time to complete  
90 minutes

Actual time to complete

# Premises, facilities and equipment

**PFE1** The premises are fit for purpose.

Please provide examples

*Examples of evidence of compliance*

- *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, visitors and patients*
- *Where appropriate policies are in place to ensure that the premises are of a standard that ensures the dignity of deceased persons*
- *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*

Self-assessment rating			
1	2	3	4

HTA rating			
1	2	3	4

**PFE2** Environmental controls are in place to avoid potential contamination.

Self-assessment rating			
1	2	3	4

Please provide examples

HTA rating			
1	2	3	4

*Examples of evidence of compliance*

- *Documented cleaning and decontamination procedures*
- *Staff are provided with appropriate protective equipment and facilities that minimise risk of contamination*
- *Appropriate Health and Safety controls are in place*

**PFE3** There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.

Self-assessment rating			
1	2	3	4

Please provide examples

*Examples of evidence of compliance*

- *Bodies, tissues, cells, consumables and records are stored in suitable environments and precautions are taken to minimise risk of damage, theft or contamination*
- *Storage conditions of critical items are monitored and recorded*
- *System to deal with emergencies on 24 hour basis*

HTA rating			
1	2	3	4

**PFE4** Systems are in place to protect the quality and integrity of bodies and body parts during transport and delivery to a destination.

Self-assessment rating			
1	2	3	4

Please provide examples

*Examples of evidence of compliance*

- *Documented policies and procedures for transport including a risk assessment of transportation*
- *A system is in place to ensure that traceability is maintained during transport*
- *Records of transportation and delivery*
- *Records are kept of material transfer agreements with recipients*
- *Records are kept of any Service Level Agreements with courier or transport companies*

HTA rating			
1	2	3	4

**PFE5** Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.

Self-assessment rating			
1	2	3	4

Please provide examples

*Examples of evidence of compliance*

- *Calibration validation and maintenance records, including any Service Level Agreements with maintenance companies*
- *Users have access to instructions for equipment and receive training in use and maintenance where appropriate*
- *Staff aware how to report an equipment problem*
- *Contingency plan for equipment failure*

HTA rating			
1	2	3	4

Estimated time to complete 25 minutes
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Actual time to complete
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# Disposal

**D1** There is a clear and sensitive policy for disposing of human organs and tissue.

Self-assessment rating			
1	2	3	4

Please provide examples

HTA rating			
1	2	3	4

*Examples of evidence of compliance*

- *Documented policy on disposal*
- *Policy is made available to the public*
- *Evidence of public engagement for policy development*
- *Compliance with Health and Safety recommendations*
- *Where appropriate the Coroners Act 1988 should be applied*

**D2** The reasons for disposal and the methods used are carefully documented.

Self-assessment rating			
1	2	3	4

Please provide examples

HTA rating			
1	2	3	4

*Examples of evidence of compliance*

- *Standard Operating Procedures for tracking the disposal of tissue that details the method and reason for disposal*
- *Disposal arrangements reflect (where applicable) the consent given for disposal*

Estimated time to complete 15 minutes
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Actual time to complete
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