

Research Compliance Report

If you store body parts, tissues or cells for research use, 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

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

D	D	M	M	Y	Y	Y	Y
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Email

Telephone

Fax

Job title

Employer

Establishment's name

Address of premises
where licensed activity
is to take place

Postcode

Activity to be licensed The storage of 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

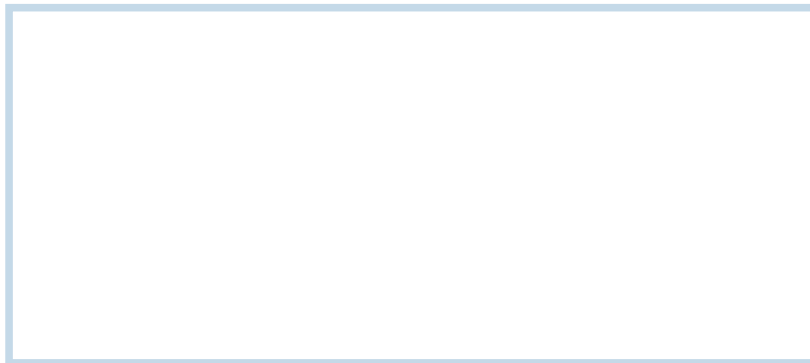
Establishment name

Educational or professional qualifications

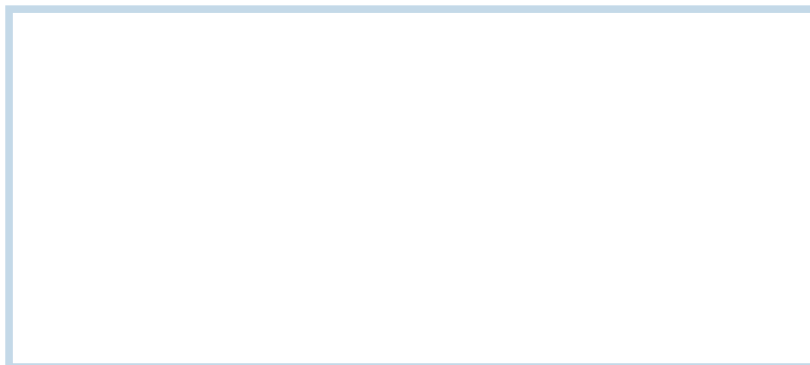
Membership of relevant professional bodies (please provide registration numbers where applicable)

Details of any other relevant experience including managerial experience and training

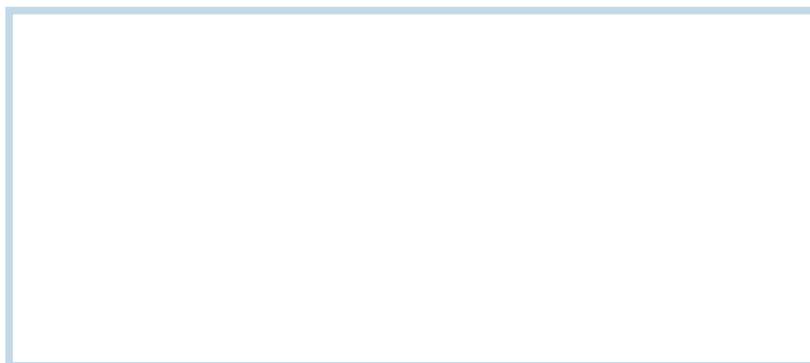
With regard to the organisational structure of the establishment, please indicate the lines of responsibility between the DI and any persons working under the licence



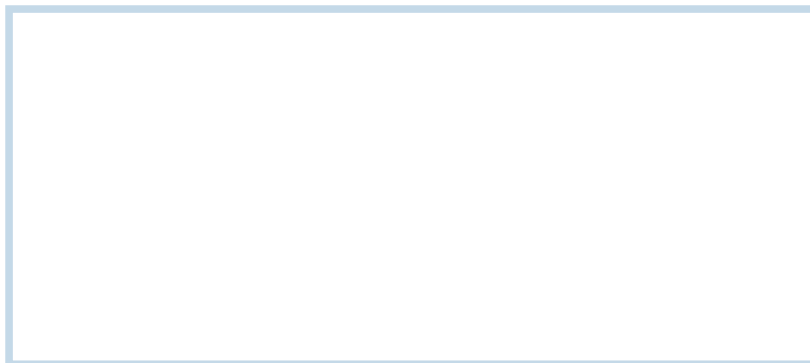
Please explain your involvement in ensuring that staff who will work under the licence are appropriately qualified and trained in techniques relevant to their work and that they are continuously updating their skills



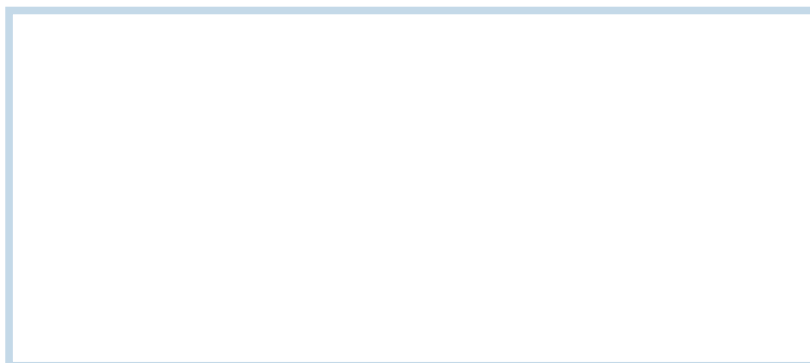
Please explain your involvement in governance and quality management activities within the establishment



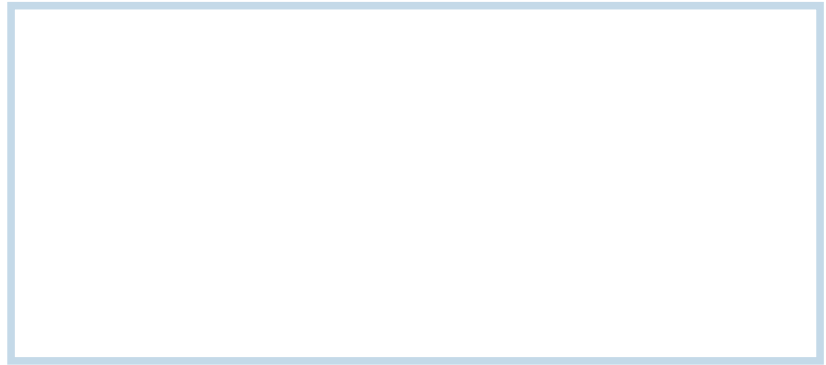
Please explain why you think you are suitable for the role of DI



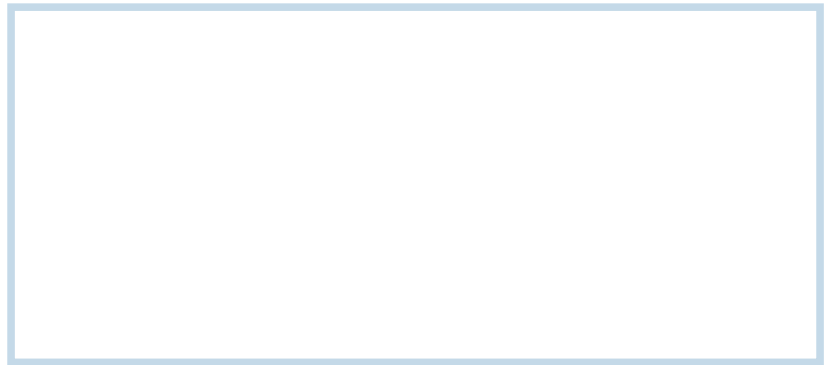
Names of person(s) who have consented to be designated on the licence (where establishment is applying for a licence(s) on one premises)



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 activity will be carried out under my supervision Yes No
- c) I accept I am responsible for securing that the other persons to whom the licence applies are suitable persons to participate in the carrying out of the licensed activity 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 activity Yes No
- e) I accept I am responsible for compliance with the conditions of any licence 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

What is the range of body parts, tissues or cells are collected or stored?

- Surplus diagnostic material
- Specific body parts, tissue or cells type(s),

If specific types, please identify tissue(s) collected

Do you store material obtained from the living and / or the deceased?

- Living
- Deceased

How are the body parts, tissues or cells stored?

- Refrigerated
- Frozen
- Fixed and frozen
- Fixed and stored at room temperature
- Liquid nitrogen storage
- Other, please describe

What types of procedures are carried out at the establishment?

- Donor selection
- Consent
- Procurement
- Storage
- Distribution
- Import / export

- Distribution
- Local
 - Regional
 - National
 - European Community
 - European Economic Area
 - Other international destination

Do you store samples on the behalf of other organisations, and if so how many organisations are you storing on behalf of?

Approximately how many samples are collected each year?

Approximately how many samples are distributed each year?

To assist the HTA, please provide a short synopsis describing the activities undertaken by the establishment

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

Information about inspection and accreditation

Do the premises where the licensable activity takes place have any 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 CPA

Date

Accredited ISO / 9000

Date

Accredited Investors in People

Date

GMP

Date

Further information:
(e.g. explaining the activities covered by the accreditation date of last inspection)

Does the establishment have any other form of accreditation? If yes, please describe, explain the activities covered by the accreditation and date of last inspection

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 body parts, tissue or cells 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 HT 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 with the requirements of the HT Act 2004 and the HTA's Code of Practice*
- *Consent procedures have been ethically approved*

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, appropriate to the situation*
- *Consent procedures have been ethically approved*

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 are in place*

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 distribution body parts, tissues or cells.

Self-assessment rating			
1	2	3	4

Please provide examples

Examples of evidence of compliance

- *A process is in place to review the release of body parts, tissue and cells to other organisations*
- *An agreement is in place between the establishment and the organisation to whom the body parts, tissues or cells are supplied regarding the tracking and use of material and eventual disposal or return*

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 parts, tissues or cells were acquired, and where from, the consent obtained, the uses to which the body parts, tissues or cells were put, when the 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 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 assessment are reviewed when appropriate*
- *Staff can access risk assessments and are made aware of local hazards at training*

Estimated time to complete 90 minutes
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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, students and visitors*
- *The premises are maintained, 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 body parts, tissues, cells, consumables and records.

Self-assessment rating			
1	2	3	4

Please provide examples

HTA rating			
1	2	3	4

Examples of evidence of compliance

- *Body parts, tissues and cells, 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*
- *Storage conditions of critical items are monitored and recorded*
- *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 body parts, tissues and cells during transport and delivery to a destination.

Self-assessment rating			
1	2	3	4

Please provide examples

HTA rating			
1	2	3	4

Examples of evidence of compliance

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

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

Self-assessment rating			
1	2	3	4

Please provide examples

HTA rating			
1	2	3	4

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*

Estimated time to complete
25 minutes

Actual time to complete

Disposal

D1 There is a clear and sensitive policy for disposing of human body parts and tissues.

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*

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 body parts, tissues and cells 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
