

Application guidance for licence applications for the pathology sector

The following activities will need to be licensed:

- The making of a post mortem examination
- Storing the body of a deceased person, or 'relevant material'¹ from a human body for use for a Scheduled Purpose²
- Removal from the body of a deceased person material of which the body consists or which it contains for use for a Scheduled Purpose other than post mortem or transplantation.

General

1. These notes are intended as a general guide to those who are considering applying for licences under the Human Tissue Act 2004 (HT Act). They set out the legal framework of the licensing system and the application process as well as providing some advice on the completion of the application form. This advice is for guidance purposes only.
2. The Human Tissue Authority (HTA) was established under the HT Act 2004. The HTA will license and inspect a number of activities to ensure compliance with the HT Act. These activities include: anatomy, post mortems, removal of tissue, storage of tissue and public display for example in museums.

¹ See S.53 of the HT Act for definition of 'relevant material'.

² The scheduled purposes which apply to this storage licence are as follows:

- Determining the cause of death
- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
- Research in connection with disorders, or the functioning , of the human body
- Clinical audit
- Quality assurance
- Establishing after a person's death the efficacy of any drug or other treatment administered to him
- Education or training relating to human health
- Public Health Monitoring

3. The HTA is also the Competent Authority in the UK under the European Tissue and Cells Directive 2004/23/EC (EUTCD) (a role shared with the Human Fertilisation and Embryology Authority), with responsibility for licensing the storage of human tissue. In addition to the storage of cornea, heart valve, bone, tendons, skin and haemopoietic stem cells, this requirement extends to the storage of blood vessels (e.g. iliac vessels taken from liver donors), pancreatic islets and any other tissue or cells that are intended for human application. The licensing scheme applies to the storage of cells and tissues in NHS and private hospitals, universities and the commercial sector. Blood and blood products are excluded as these are covered by a separate EU Directive.
4. Detailed technical annexes to the EUTCD are in preparation and will be implemented in 2007. These will cover the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells.
5. On 7 April 2006, the HTA under section 16(2)(e)ii commenced regulating the storage of human cells and tissues for human application. From the 1 September the remainder of the HT Act will be commenced and we will begin licensing the activities as set out above.
6. The HTA recognises that most establishments carrying out post mortem examinations are likely to undertake more than one activity. Consequently, the three potential licensable activities have been clustered together.

Do you need to apply for a licence?

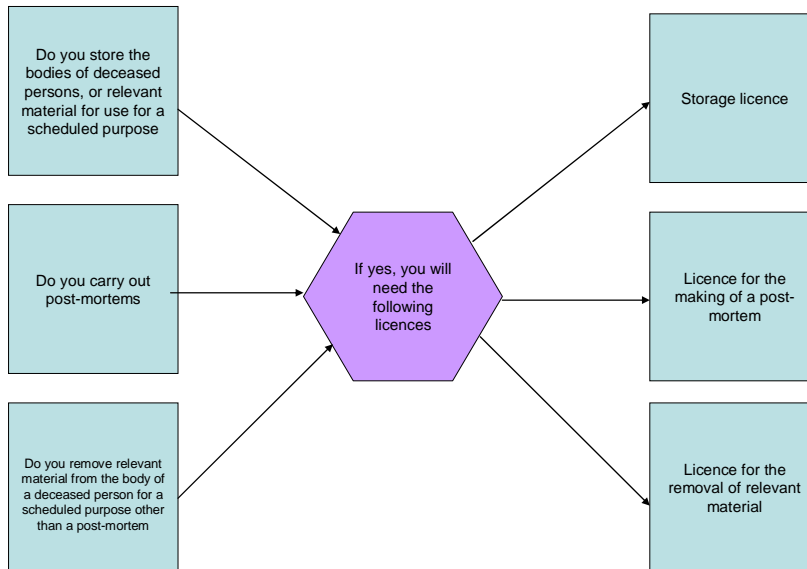
7. From 1 September 2006 the HTA under Section 16 will commence regulating:
 - the making of a post mortem examination;
 - storing the body of a deceased person, or 'relevant material'³ from a human body for use for a Scheduled Purpose⁴;
 - removal from the body of a deceased person material of which the body consists or which it contains for use for a Scheduled Purpose other than post mortem or transplantation.

³ See S.53 of the HT Act for definition of 'relevant material'.

⁴ See HT Act 2004 Schedule 1 (Scheduled Purposes) Part 1 and Part 2

The scheduled purposes which apply to this storage licence are as follows: Determining the cause of death; Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); Research in connection with disorders, or the functioning, of the human body; Clinical audit; Quality assurance; Establishing after a person's death the efficacy of any drug or other treatment administered to him; Education or training relating to human health; Public Health Monitoring.

Flowchart showing whether licences are required



8. Before granting a licence the HTA must have received a formal application. Only one combination of activity and premises can be covered per licence. Where the organisation covers multiple sites (e.g. as a regional storage point storing tissues collected from a number of individual establishments), the HTA will accept a single application, provided that:
 - The same DI has been appointed
 - The sites work to the same standard operating procedures.
9. The HTA will issue separate licences covering the main site and each satellite site.
10. Satellite sites are those establishments (generally small) which store material on behalf of a parent organisation, under the supervision of the Designated Individual (DI) using the same Standard Operating Procedures. Each satellite site will have its own licence which will incur a reduced fee.
11. For ease-of-use the HTA intends that the application should be completed online via the HTA website.

- 12. Applicants should note that any incorrect or misleading information provided in an application could lead to the revocation of any licence granted.**

Completing and submitting a licence application

13. Licence applications are made by submitting an application form via the HTA website. Applicants will need to acquire a login ID to enable an online submission.

The application form

14. The application form contains the following three distinct sections:

- Information about the DI and the Licence Holder
- Information about the Establishment
- Compliance Report.

The Compliance Report

15. The Compliance Report contains four categories of standards that the HTA require applicants to assess and evaluate their performance against. The categories are:

- Consent
- Governance and Quality Systems
- Premises, Facilities and Equipment
- Disposal.

16. The compliance reporting method has been chosen because it has been shown to be a successful way of engendering change and driving up standards within a regulated sector. It empowers the regulated sector to identify areas for improvement and implement changes to achieve them.

Evaluation of the Compliance Report

17. The Compliance Report will be evaluated using the qualitative and numerical evidence provided by the applicant. The evaluation will enable the HTA to assess the risks associated with areas of non-compliance so that an informed and proportionate licensing decision can be made.

18. The establishment should assess its performance against the standards using a scale of 1–4 (the 'Examples of Evidence of Compliance' notes beneath each question are designed to help determine the appropriate

rating). The same scale of 1–4 will be used by the HTA when evaluating applications. The scores will not be cumulative: each standard and the evidence for it will be evaluated on a case by case basis. The ratings are as follows:

19.

1	Standard not met
2	Standard partially met
3	Standard almost met
4	Standard fully met or exceeded

20. In addition to the numerical score a narrative statement should also be included to support and explain the rationale for the chosen rating, for example a brief description of how the standard is being met or if the standard is not being fully met what is being done to achieve the standard. It would be also be appropriate to indicate key strengths or areas identified as needing improvement.

21. The HTA may contact applicants to provide additional information at any stage in the process (for example to clarify the response given to particular standards).

22. The HTA does not require any evidence to be supplied with the application. The report should simply indicate what evidence is available that demonstrates compliance with a given standard. The HTA may ask to see examples of this evidence at any stage.

Important note

23. By 1 September 2006 the HTA must issue licences to all establishments that carry out post mortem examinations, store the bodies of deceased persons, or 'relevant material'¹ from a human body for use for a Scheduled Purpose¹, and/or the removal from the body of a deceased person material of which the body consists or which it contains for use for a Scheduled Purpose other than post mortem or transplantation. Taking into account the timescale involved it is not possible for the HTA to make an assessment of all the applications received before issuing a licence. It has been decided that to overcome this difficulty and in order to ensure that legal requirements are being met, the HTA will upon receipt of an application automatically issue a 'deemed licence'. After the issue of the deemed licence an evaluation of the applications (as described above) will take place during September. Following the evaluation establishments will be sent a proposed licence for acknowledgement. If the terms of the

proposed licence are acknowledged the licence will become valid and the deemed licence will automatically be revoked.

Timeframes

24. It is anticipated that (other than in the situation described above) once an application for a licence has been received it will take the HTA approximately 28 days to issue a proposed licence.

Receipt of the proposed licence and the right to make representations

25. In accordance with the HT Act the holder of the licence and / or the DI have 28 calendar days beginning with the day on which the notice of the proposed licence was given in order to give notice of the wish to make representations. The Act does not specify how this notice is to be given: accordingly, verbal notice (e.g. by telephone) would be sufficient to trigger the right to make representations. Such notice must be given to one of the following persons, the Licensing Manager, the Inspections Manager or the Head of Regulation, who will make a written contemporaneous note of any such verbal request. They will then notify the licence holder and/or DI in writing of the receipt of that request.

Issuing the substantive licence

26. It is a pre-condition to the grant of a substantive licence that a copy of the conditions to be imposed by the licence have been shown to and acknowledged in writing by:

- the applicant for the licence, and;
- where different, the proposed DI.

27. Once the HTA has received the written acknowledgement of the terms of the proposed licence a substantive license for a fixed duration will be issued.

The following section gives specific help for filling in the Application Form and Compliance Report.

Help: Part 1 – Application Form

Application to be Designated Individual (DI)

Section help

28. If you require additional information about the role of the DI and whether you are suitable, please refer to the separate guidance issued by the HTA.

Question help

30. *Establishment name*

Include department name if applicable.

31. *Establishment address*

This should be the address of the main site if you are also applying on behalf of satellite sites. Paragraph 2 (3) (a) of Schedule 3 of the HT Act prohibits the HTA from granting a licence for an activity to be conducted on premises at different places. The HTA has taken the view that to enable accountability for any problems at a particular site, there should be clarity between the licensable activity and specific premises. An application for a licence should specify the premises where the licensed activity is to take place. Where the licensed activity will take place in premises at more than one place, a separate licence will need to be issued. However to streamline the process and reduce the burden for applicants, wherever possible a single application for multiple licences may be made. Please see section below for listing satellite sites.

32. *Activities to be licensed*

If material is removed during a post mortem for purposes other than the making of a post mortem, a separate licence for removal of material from the body of a deceased person will be required.

33. *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.*

The HT Act requires that the HTA must be satisfied that the DI will supervise the licensed activity (see Schedule 3 6 (3) (a) of the HT Act). Therefore the HTA would like to know the relationship between the DI and

the Person(s) Designated on the licence as well as the relationship between the DI and those working under the licence. If you need further advice regarding the role of the DI and Persons to be Designated on the licence, please refer to separate guidance issued by the HTA.

33. *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.*

The HT Act requires that the DI ensures suitable practices are carried out by those performing the licensed activity; training of staff is an important part of this. Therefore, the HTA want to understand the role of the DI in ensuring staff working under a licence are suitably qualified and trained.

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

The HT Act allows the DI to designate persons on their licence with their agreement. If you need further advice regarding Persons to be Designated on the licence, please refer to separate guidance issued by the HTA.

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

Satellite sites are those establishments (generally small) which store material on behalf of a parent organisation, under the supervision of the DI using the same Standard Operating Procedures. Each satellite site will have its own licence which will incur a significantly reduced fee.

36. *Names of person(s) who have consented to be Designated on the licence at the satellite premises.*

If you wish to have a Person(s) Designated on the licence for the satellite premises you should list the name of the person(s) indicating which satellite site licence they are to be designated on. If you need further advice regarding Persons to be Designated on the licence, please refer to separate guidance issued by the HTA.

Declaration

37. It is important that you read through and acknowledge each of the statements.

Application to be Licence Holder

Section help

38. If someone other than the DI applies for a licence they will need to include their details. The applicant can be a person or a corporate body and must be suitable to hold the position of Licence Holder (if the applicant is a corporate body please see application to be a Corporate Licence Holder).

The applicant must have the consent of the proposed DI in making the application. If you require additional information about the role of the Licence Holder please refer to separate guidance issued by the HTA.

Declaration

39. It is important that you read through and acknowledge each of the statements.

Application to be a Corporate Licence Holder

Section help

40. If a corporate body is the proposed Licence Holder, details will need to be given here. The applicant can be a person or a corporate body and must be suitable to hold the position of Licence Holder (if the applicant is a person, please see section on application to be a Licence Holder). The applicant must have the consent of the proposed DI in making the application. If you require additional information about the role of the Licence Holder please refer to separate guidance issued by the HTA.

Declaration

41. It is important that you read through and acknowledge each of the statements.

Establishment information

Question help

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

For example, the synopsis could include the following information:

- How long have the activities been taking place
- Who uses the facility
- How does it relate or interact with other establishments?

42. *Please document how many adverse events have occurred in your establishment in past 12 months.*

This information is necessary to assist the HTA in evaluating the Compliance Report and making a risk assessment on the basis of the

evaluation. An adverse event is any event that:

- Caused harm or had the potential to cause harm to staff or visitors.
- Led to or had the potential to lead to a breach of security of the premises and the contents contained therein.
- Caused harm or had the potential to cause harm to stored human tissue (including loss).
- Any other event that gave rise to an internal inquiry.

Once an establishment is licensed under the HT Act any breach of the HT Act or the Code of Practice will be considered to be an adverse event. As a matter of good practice a mechanism for logging these events should be developed.

Help: Part 2 – Licensing Standards

43. The licensing standards are separated into four main themes; consent, governance and quality systems, premises, facilities and equipment and disposal. Each section must be completed. However, establishments that have MHRA/CPA/JACIE accreditation should score individual standards as 4 where applicable, to indicate full compliance. Scoring is necessary to enable the submission of the application.

Consent

Section help

44. The principle of informed consent underpins the purpose of the HT Act 2004. It is therefore important for all those licensed under the HT Act to demonstrate how the provisions regarding consent are being implemented to reflect this requirement. Further advice and guidance is available on the HTA website, including Codes of Practice.

Standard help

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

If the establishment obtains consent then please explain how you ensure that the process complies with HT Act and the Codes of Practice. If a third party is obtaining consent on your behalf then please indicate the agreements you have in place with them to ensure that the process complies with the HT Act and the Codes of Practice.

Governance and quality systems

Section help

45. The HTA wants the establishment to demonstrate that it has a system that ensures the provision of safe tissue with reliable quality. MHRA/CPA/JACIE accredited establishments may omit answers to GQ1–4 (inclusive) and GQ8, provided that they are able to submit a self-assessment score of 4. Scoring is necessary to enable the submission of the application.

Standard help

46. GQ1 – *All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process.*

MHRA/CPA/JACIE accredited establishments may omit an answer to this question provided that they are able to submit a self-assessment score of 4. Non-MHRA/CPA/JACIE establishments should describe whether they have policies in place including donor selection; consent; data protection and confidentiality; tissue processing and storage; labelling; equipment maintenance and calibration; cleaning, air control. Please state whether the documents are dated and if they are reviewed on a regular basis.

47. GQ2 – *There is a documented system of quality management and audit.* Evidence of compliance should demonstrate that there is a system in place to ensure that any changes in the operating procedures are made available to staff.

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

The HT Act requires that the DI ensures suitable practices are carried out by those performing the licensed activity; training of staff is an important part of this. MHRA/CPA/JACIE accredited establishments may omit an answer to this question provided that they are able to submit a self-assessment score of 4. Scoring is necessary to enable the submission of the application. Non-MHRA/CPA/JACIE accredited establishments should describe what training is made available to staff and also detail whether they have a training manual, training records and personal development plans for individual staff members.

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

Establishments should describe the system in place to manage records, including the presence of any policies for the creation, retention and destruction of records.

Establishments should also describe if a system is in place to ensure the accuracy of records.

50. GQ.6 – *A coding and record system facilitates traceability of bodies, body parts, tissue and cells, ensuring a robust audit trail.*

Any tissues or cells which are stored and supplied should be traceable. Establishments should specifically describe whether they have a system in place which enables this requirement. Applicants should state whether any updates to the system are planned or anticipated. The establishment's procedures should make it clear where another organisation takes over responsibility for ensuring the traceability of tissues and cells intended for human applications.

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

Establishments should state whether they have carried out and recorded risk assessments for practices and processes carried out within the establishment. They should also describe:

- How staff can access the risk assessments and are made aware of their contents.
- How often the risk assessments are reviewed and how this review process is recorded.

Any planned changes to assessing and reviewing risk assessment should be included.

Premises, facilities and equipment

Section help

52. The HT Act states that licensed activities should be carried out in suitable premises. The HTA must satisfy its duty in determining that the premises are suitable for the activity undertaken before a licence can be offered to an applicant.

Standard help

53. PFE1 – *The premises are fit for purpose.* Establishments should describe briefly if any assessment has been carried out to ensure the premises / facilities are fit for purpose.

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

CPA accredited establishments may give a rating of 4 for this question.

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

This standard is concerned with how secure the premises are and the overall environment in which cadavers / body parts are stored. Centres should describe what policies and practices that are in place to ensure materials are securely stored in a controlled environment. They should also give details of any monitoring systems in place to maintain this controlled environment. Any planned updates to policies and procedures should be described.

56. PFE4 – *Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to its destination.*

Establishments should describe how they ensure the quality and integrity of cadavers / body parts during transport. They should describe whether any risk assessment has been carried out and any action taken to mitigate risks during transport. Any planned updates to procedures should be described.

Disposal

Section help

57. Disposal of material comes under the remit of the HTA following the commencement of the HT Act. The HTA has therefore published guidance on this topic which is available within the “Code of Practice on the removal, storage and disposal of human organs and tissue” on the HTA website.

Defined terms used within the application

Adverse event – An adverse event is any event that:

- Caused harm or had the potential to cause harm to staff or visitors
- Led to or had the potential to lead to a breach of security of the premises and the contents contained therein
- Caused harm or had the potential to cause harm to stored human tissue (including loss)
- Gave rise to an internal inquiry.

Once an establishment is licensed under the HT Act any breach of the HT Act or the Code of Practice will be considered to be an adverse event.

CPA – Clinical Pathology Accreditation.

Designated Individual (DI) – refer to separate guidance issued by the HTA.

JACIE (Joint Accreditation Committee) – International Society for Cellular Therapy and European Group for Blood and Marrow Transplantation

MHRA – Medicine and Healthcare Products Regulatory Agency.

Scheduled Purposes - The activities relating to the removal, storage and use of human organs and other tissue, listed in Schedule 1 of the HT Act that require consent.

Service Level Agreements – formal agreement between a service provider and a customer that specifies, usually in measurable terms what level of service will be supplied.

Standard Operating Procedures – Standard Operating Procedures: established procedures to be followed in carrying out a given operation or in a given situation.

Storage – Maintaining the product under appropriate controlled conditions until distribution.