Licence application form for activities for removal of samples from the deceased

for testing

This application form is to be licensed for activities related only to removing samples from the deceased for testing. HTA licences for this activity are for a fixed term of 12 months. You can apply to the HTA to revoke the licence, at any point.

Application to be licensed for:

* 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 for a Scheduled Purpose other than transplantation (where removal is not in the course of a post-mortem examination)

Contact the HTA before completing this form if:

* bodies may be stored on your premises for any other purpose(s) beyond your normal requirements; or,
* the sample(s) may be stored on your premises for more than seven days before being sent for testing.

In these cases, a licence for storage may also be required.

Please refer to the HTA’s website for:

* [The role and responsibilities of Designated Individuals and Licence Holders under the Human Tissue Act 2004](http://www.hta.gov.uk/useful-information-dis-and-named-contacts-0)
* [HTA guidance on consent and licensing for removing samples from the deceased for testing](https://www.hta.gov.uk/removing-samples-deceased-testing)

Submit the completed application form and supporting documents to: **licensing.enquiries@hta.gov.uk**

For urgent application, call the HTA on 020 7269 1900

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| Section 1 – Establishment Information (hub site) |  |
| **Premises name**  |  |
| **Premises address (include postcode)**  |  |
| **Parent organisation (if applicable)** |  |
| **Synopsis – provide details of:*** What samples will be taken?
* How will the samples be taken?
* Who will do this?
* Whether you will be storing bodies for other purpose(s) outside your normal requirements?
* What is the maximum time samples will be on your premises **before** being sent off-site?
* How your facility relates to, or interacts with, other establishments, for example links with other establishments for testing.

*Contact the HTA if:** *bodies may be stored on your premises for any other purpose(s) beyond your normal requirements; or,*
* *the sample(s) may be stored on your premises for more than seven days before being sent for testing.*
 |  |
| **Persons Designated (PDs) for hub** **site** Provide details of PDs for the licence. PD(s) should be different to the DI and LH/CLHc.*(Copy and paste additional rows for more PDs, as needed)* |
| **Name****Job title** **Email address****Telephone number** |  |

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| Section 2 – Satellite Sites |
| **Does the establishment have any satellite sites?** Yes [ ]  *Complete this section for each satellite site (Copy and paste section, as needed)* No [ ]  *Do not complete section 2 of this form* |
| **Satellite site premises name**  |  |
| **Satellite site address (include postcode)**  |  |
| **Explain how the satellite site links to the governance of the hub site** |  |
| **Short synopsis of how the facility will be used** – see section 1 for the Details of: to include here. |  |
| **Relevant further information** |  |
| **Persons Designated (PDs) for satellite** **site** *(Copy and paste additional rows for more PDs, as needed)* |
| **Name****Job title** **Email address****Telephone number** |  |
| **Name of person who completed this form *(must be DI or LH)*:** | **Date:** DD/MM/YYYY |
| ****Section 3 – Application to be Designated Individual (DI)****To be completed by proposed DI |
| **Title, Forename(s), Surname** |  |
| **Other names previously known by** |  |
| **Correspondence address (include postcode)** |  |
| **Email address** |  |
| **Telephone number(s)** |  |
| **Job title** |  |
| **Have you ever applied to be a DI for another establishment?*****If yes, name and application reference:*** | Yes [ ]  No [ ]  |
| **Educational and/or professional qualifications:**  |  |
| **Membership of relevant professional bodies and registration numbers where applicable:**  |  |
| **Other relevant experience, including managerial experience and training:** |  |
| **Lines of responsibility between the DI and any persons working under the licence:** |  |
| **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:** |  |
| **Involvement in governance and quality management activities at the establishment, including any meetings with staff:** |  |
| **Explain why you think you are suitable for the role of DI:** |  |
| Declaration by proposed Designated IndividualAny 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 |

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| Section 4 (Complete section 4i or 4ii) |
| 4i – Application to be Individual Licence Holder (LH) This section is to be completed when an individual person is applying to be the LH.  |
| **Title, Forename(s), Surname** |  |
| **Other names previously known by** |  |
| **Correspondence address (include postcode)** |  |
| **Email address** |  |
| **Telephone number(s)** |  |
| **Job title** |  |
| **Educational and/or professional qualifications** |  |
| **Membership of relevant professional bodies and registration numbers where applicable** |  |
| **Other relevant experience, including managerial experience and training** |  |
| **Explain why you think you are suitable for the role of the Licence Holder** |  |
| Declaration by proposed Licence HolderAny 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 |

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| 4ii – Application to be Corporate Licence Holder (CLH) This section is to be completed when a corporate body is applying to be the LH, with a contact acting on behalf of the corporate body (CLHc).  |
| *Details of person applying to be the CLHc on behalf of the Corporate Licence Holder:* |
| **Title, Forename(s), Surname** |  |
| **Other names you have been known as** |  |
| **Correspondence address (include postcode)** |  |
| **Email address** |  |
| **Telephone number(s)** |  |
| **Job title** |  |
| **Full name of corporate body to be the Corporate Licence Holder:** |  |
| **Trading name or business name, if different from company name:**  |  |
| **Type of corporate body and relevant details:** | [ ]  Funeral Director[ ]  Other (e.g. Local Authority, Hospice) *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, provide details** |  |
| **Explain why the corporate body is suitable for the role of the Corporate Licence Holder** |  |
| Declaration by proposed Corporate Licence HolderAny 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 of proposed CLHc:** | **Date:** DD/MM/YYYY |

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| Section 5 – Summary and Compliance self-assessment |
| Consent Consent standards apply to removal activity, unless under coronial or police authority. [ ]  Removal and use of samples will be under coronial or police authority – *the consent section does not apply, proceed to Governance and Quality systems standards.*  |
| ***Refer to*** [***HTA Code of Practice B***](https://www.hta.gov.uk/sites/default/files/Code%20B.pdf) ***for information on the consent requirements.***Provide details of:* Documented procedure and policy for seeking consent;
* When consent for removal and use of the sample will be sought from the family;
* Information that will be provided to the family of the deceased;
* Options that will be given to the family for future use of the samples *(N/A if the samples will be disposed of after initial testing)*;
* How you will ensure that the appropriate person is giving consent; and,
* How consent will be documented.

Or, if documented procedures and policies describing this information are submitted with the application – please list the document name and sections where this information is detailed: |
| C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA’s Codes of Practice |
| a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA’s Codes of Practice. | [ ]  Not met[ ]  Met |
| b)There is a documented standard operating procedure (SOP) detailing the consent process. | [ ]  Not met[ ]  Met |
| c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA’s Codes of Practice. | [ ]  Not met[ ]  Met |
| d)Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives. | [ ]  Not met[ ]  Met |
| e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained. | [ ]  Not met[ ]  Met |
| f) The deceased’s family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds. | [ ]  Not met[ ]  Met |
| g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided. | [ ]  Not met[ ]  Met |
| C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent |
| Provide details of:* Who will seek consent for removal and use of samples from the body; and,
* How they will be trained and assessed as competent to seek consent, and how this will be recorded.

Or, if documented procedures and policies describing this information are submitted with the application – please list the document name and sections where this information is detailed: |
| a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA’s Codes of Practice. | [ ]  Not met[ ]  Met |
| b) Records demonstrate up-to-date staff training. | [ ]  Not met[ ]  Met |
| c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual. | [ ]  Not met[ ]  Met |
| d) Competency is assessed and maintained. | [ ]  Not met[ ]  Met |
| Governance and Quality Systems |
| GQ1 All aspects of the establishments work are governed by documented policies and procedures |
| Provide details of:* Documented procedures and policies for the following:
1. how samples will be removed from the body;
2. systems of traceability of bodies and samples;
3. lone working (if applicable);
4. transfer samples off site or to other establishments.

Or, if documented procedures and policies describing this information are submitted with the application – please list the document name and sections where this information is detailed:* How staff will be made aware of, and acknowledge the SOPs and policies; and,
* Governance meetings that will be held with staff working under the licence (frequency and topics to be covered).
 |
| a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.  | [ ]  Not met[ ]  Met |
| d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use. | [ ]  Not met[ ]  Met |
| e) There is a system for recording that staff have read and understood the latest versions of these documents. | [ ]  Not met[ ]  Met |
| f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity. | [ ]  Not met[ ]  Met |
| g) All areas where activities are carried out under an HTA licence are incorporated within the establishment’s governance framework. | [ ]  Not met[ ]  Met |
| h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff. | [ ]  Not met[ ]  Met |
| GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks |
| Provide details of:* How people involved in removing samples from the body will be trained and assessed as competent in the procedures and how this will be recorded.
 |
| a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised. | [ ]  Not met[ ]  Met |
| b) There are clear reporting lines and accountability. | [ ]  Not met[ ]  Met |
| c) Staff are assessed as competent for the tasks they perform. | [ ]  Not met[ ]  Met |
| f) There is a documented induction and training programme for new mortuary staff. | [ ]  Not met[ ]  Met |
| g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment’s policies and procedures. | [ ]  Not met[ ]  Met |
| GQ4 There is a systematic and planned approach to the management of records |
| Provide details of:* How records relating to licensed activities will be stored and maintained;
* Whether there is an SOP covering management of records; and,
* Systems to ensure data protection, confidentiality and public disclosure.
 |
| a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record. | [ ]  Not met[ ]  Met |
| b) There are documented SOPs for record management which include how errors in written records should be corrected. | [ ]  Not met[ ]  Met |
| c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing). | [ ]  Not met[ ]  Met |
| GQ5 There are systems to ensure that all untoward incidents are investigated promptly |
| ***Refer to the HTA for*** [***guidance on incident reporting requirements***](https://www.hta.gov.uk/policies/post-mortem-hta-reportable-incidents)***.***Provide details of:* Documented procedure in place for identifying, reporting and managing incidents.

**Or,** if the documented procedure describing this information is submitted with the application – please list the document name and sections where this information is detailed:* How staff will be made aware of requirements to report incidents and near-miss incidents to the HTA and the timeframe to do this; and
 |
| a) Staff know how to identify and report incidents, including those that must be reported to the HTA. | [ ]  Not met[ ]  Met |
| b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents. | [ ]  Not met[ ]  Met |
| c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed. | [ ]  Not met[ ]  Met |
| d) Information about incidents is shared with all staff to avoid repeat errors. | [ ]  Not met[ ]  Met |
| e) The establishment adopts a policy of candour when dealing with serious incidents. | [ ]  Not met[ ]  Met |
| GQ6 Risk assessments of the establishment’s practices and processes are completed regularly, recorded and monitored |
| **Submit documented risk assessment(s) with licence application.** |
| a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis. | [ ]  Not met[ ]  Met |
| b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed. | [ ]  Not met[ ]  Met |
| c) Significant risks, for example to the establishment’s ability to deliver post-mortem services, are incorporated into the Trust’s organisational risk register. | [ ]  Not met[ ]  Met |
| Traceability |
| T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail |
| Provide details of:* Identification tags that will be attached to the body, and which identifiers of the deceased will be on these labels;
* How the identification of the deceased will be checked against the consent documentation before the sample is removed from the body (who will do this and what identifiers of the deceased will be checked);
* How samples will be labelled (including which identifiers of the deceased);
* How removal of samples will be documented?
* Process for recording samples have been sent off-site.

Or, if documented procedures describing this information are submitted with the application – please list the document name and sections where this information is detailed: |
| a) Bodies are tagged/labelled upon arrival at the mortuary. | [ ]  Not met[ ]  Met |
| b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records). | [ ]  Not met[ ]  Met |
| c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier. | [ ]  Not met[ ]  Met |
| e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises. | [ ]  Not met[ ]  Met |
| g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). | [ ]  Not met[ ]  Met |
| h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements. | [ ]  Not met[ ]  Met |
| Premises, Facilities and Equipment |
| PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue. |
| Provide details of:* Where in your premises the samples will be taken from the body;
* Details of security measures to restrict access and overlooking to this area; and;
* How the facility is cleaned, by who and how this is recorded.
 |
| a) The premises are clean and well maintained. | [ ]  Not met[ ]  Met |
| b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors. | [ ]  Not met[ ]  Met |
| c) There are documented cleaning and decontamination procedures and a schedule of cleaning. | [ ]  Not met[ ]  Met |
| d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access). | [ ]  Not met[ ]  Met |
| e) Security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access. | [ ]  Not met[ ]  Met |
| PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored |
| Provide details of:* Personal protective equipment that will be worn by staff when undertaking removal of samples from the body.

If documented procedures describing this information are submitted with the application – please list the document name and sections where this information is detailed:* Equipment relevant to the activity (e.g. trolleys);
* How this equipment is maintained, and records kept of this.
 |
| a) Items of equipment in the mortuary are in a good condition and appropriate for use. | [ ]  Not met[ ]  Met |
| b) Equipment is appropriate for the management of bariatric bodies. | [ ]  Not met[ ]  Met |
| d) Staff have access to necessary PPE. | [ ]  Not met[ ]  Met |
| e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation. | [ ]  Not met[ ]  Met[ ]  N/A |
| f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept. | [ ]  Not met[ ]  Met |

# Checklist before submitting licence application to the HTA

[ ]  Completed licence application form

[ ]  Completed risk assessment(s) of licensed activities applied to be conducted

[ ]  Documented policies and procedures referenced in this application form