Removal Licence Application

If you remove relevant material from the body of a deceased person (otherwise than in the course of an anatomical examination or a post-mortem examination) for use for a scheduled purpose other than transplantation, you can apply for a licence using this application form.

Please refer to the HTA’s website for:

* [guidance on completing this application form](https://www.hta.gov.uk/policies/licence-application-guidance)
* [information about HTA licensing](https://www.hta.gov.uk/guidance-professionals/licensing-information)
* [the role and responsibilities of Designated Individuals and Licence Holders under the Human Tissue Act](https://www.hta.gov.uk/policies/designated-individuals-and-licence-holders-under-human-tissue-act)

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| Establishment Information  |
| A licence application must specify the premises where the activities are to take place.  |
| Premises name |  |
| Department |  |
| Address | Postcode: |
| Type of organisation | [ ]  Limited companyCompany registration number:[ ]  Sole proprietorName and address:[ ]  Public Limited CompanyCompany registration number:[ ]  CharityCharity registration number:[ ]  PartnershipNames and addresses of partners:[ ]  NHS OrganisationPlease describe:[ ]  Other public bodyPlease describe:[ ]  Higher Education Institution[ ]  OtherPlease describe: |
| Are you applying for a continuous, or a six month temporary, licence? | Continuous  [ ]             Six Month Temporary [ ]    |
| 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: |
| Activity to be licensed | [ ]  Section 16(2)(c) – the removal from the body of a deceased person (otherwise than in the course of an anatomical examination or a post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation |
| How many staff members are involved in carrying out the licensable activity? |  |
| To assist the Human Tissue Authority, please provide a synopsis of the activities to be licensed.For example:* 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
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| How many adverse incidents have occurred in the establishment in the past 12 months? |  |
| Please provide contact details for the proposed Persons Designated on the licence  |  | Name | Email | Telephone  |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |

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| Application to be Designated Individual (DI)To be completed by proposed DIBefore completing, we recommend you read the useful information for DIs we have published on our website: <https://www.hta.gov.uk/guidance-professionals/useful-information> |
| 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 |  |
| Regarding 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 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 practices 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) 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 |  |
| 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 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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| Application to be Corporate Licence Holder (CLH) 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 applying to be the Corporate Licence Holder contact on behalf of the Corporate Licence Holder: |
| Title |  |
| Forenames |  |
| Surname |  |
| If you have been known by another name, please give details |  |
| Email |  |
| Telephone |  |
| Fax |  |
| Job title |  |
| Full name of Corporate body |  |
| Trading name or business name if different from company name |  |
| Type of organisation | [ ]  Limited companyCompany registration number:[ ]  Sole proprietorName and address:[ ]  Public Limited CompanyCompany registration number:[ ]  CharityCharity registration number:[ ]  PartnershipNames and addresses of partners:[ ]  NHS OrganisationPlease describe:[ ]  Other public bodyPlease describe:[ ]  Higher Education Institution[ ]  OtherPlease 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 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: | Date: DD/MM/YYYY |

Human Tissue Authority [Standards](http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm)

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| Consent |
| 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)  | Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA’s Codes of Practice. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| b) | Consent forms are available to those using or releasing relevant material for a scheduled purpose. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| c) | Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA’s Codes of Practice. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| d) | Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA’s Codes of Practice. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| e) | Language translations are available when appropriate. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| f) | Information is available in formats appropriate to the situation. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent. |
| a) | There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA’s Codes of Practice. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| b) | Records demonstrate up-to-date staff training. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| c) | Competency is assessed and maintained. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
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| Governance and Quality Systems |
| GQ1 All aspects of the establishment’s work are governed by documented policies and procedures as part of the overall governance process. |
| a) | Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| b) | There is a document control system. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| c) | There are change control mechanisms for the implementation of new operational procedures. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| d) | Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff*.* | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| e) | There is a system for managing complaints. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| GQ2 There is a documented system of audit. |
| a) | There is a documented schedule of audits covering licensable activities. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| b) | Audit findings include who is responsible for follow-up actions and the timeframes for completing these. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills. |
| a) | Qualifications of staff and all training are recorded, records showing attendance at training. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| b) | There are documented induction training programmes for new staff. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |

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| c) | Training provisions include those for visiting staff. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| d) | Staff have appraisals and personal development plans. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| GQ4 There is a systematic and planned approach to the management of records. |
| a) | There are suitable systems for the creation, review, amendment, retention and destruction of records.  | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| b) | There are provisions for back-up / recovery in the event of loss of records.  | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| c) | Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).  | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| GQ5 There are systems to ensure that all adverse events are investigated promptly. |
| a) | Staff are instructed in how to use incident reporting systems. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |

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| b) | Effective corrective and preventive actions are taken where necessary and improvements in practice are made. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| GQ6 Risk assessments of the establishment’s practices and processes are completed regularly, recorded and monitored. |
| a) | There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA’s Codes of Practice. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| b) | Risk assessments are reviewed regularly.  | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| c) | Staff can access risk assessments and are made aware of risks during training. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
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| Traceability |
| T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail. |
| a) | There is an identification system which assigns a unique code to each donation and to each of the products associated with it. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| b) | A register of donated material, and the associated products where relevant, is maintained.  | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| c) | An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| d) | A system is in place to ensure that traceability of relevant material is maintained during transport. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| e) | Records of transportation and delivery are kept. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| f | Records of any agreements with courier or transport companies are kept.  | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| g | Records of any agreements with recipients of relevant material are kept. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |

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| Premises, Facilities and Equipment |
| PFE1 The premises are secure and fit for purpose. |
| a) | An assessment of the premises has been carried out to ensure that they are appropriate for the purpose. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| b) | Arrangements are in place to ensure that the premises are secure and confidentiality is maintained. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| c) | There are documented cleaning and decontamination procedures.  | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| PFE2 Equipment is appropriate for use, maintained, validated and where appropriate monitored.  |
| a) | Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept. | [ ]  Not applicable[ ]  Met Not met |
| Please provide examples. |
| b | Users have access to instructions for equipment and are aware of how to report an equipment problem. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |
| c | Staff are provided with suitable personal protective equipment. | [ ]  Not applicable[ ]  Met[ ]  Not met |
| Please provide examples. |

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