**Anatomy Licence Application**

If you store anatomical specimens, former anatomical specimens or carry out anatomical examinations, 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://content.hta.gov.uk/sites/default/files/2021-06/Guide%20to%20Completion%20of%20the%20Anatomy%20Licence%20Application%20July%202017.pdf)
* [information about HTA licensing](https://www.hta.gov.uk/guidance-professionals/licensing)
* [the role and responsibilities of Designated Individuals and Licence Holders under the Human Tissue Act](https://www.hta.gov.uk/guidance-professionals/licensing/designated-individuals-and-licence-holders-under-human-tissue-act)

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

|  |
| --- |
| **Establishment information** |
| A licence application must specify the premises where the activities are to take place; this should be the address of the main site. Where the licensed activity will take place at more than one premises (i.e. a main site with remote satellite sites), a separate satellite licence will be needed for each site. |
| 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 licence? | Yes [ ]  No [ ] If yes, please state the existing licence number you are applying to replace: |

|  |  |
| --- | --- |
| Activities to be licensed | [ ]  Section 16(2)(a) - The carrying out of anatomical examination[ ]  Section 16(2)(c) - The removal of relevant material from the body of a deceased person of relevant material of which the body consists or which it contains for use of a Scheduled Purpose other than transplantation (where removal is not in the course of a post mortem examination)[ ]  Section 16(2)(d) - The storage of an anatomical specimen [ ]  Section 16(2)(e)(i) and (ii) - 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, other than the storage of an anatomical specimen |
| What are the range of anatomical specimens collected or stored (e.g. temporal bone)? |  |
| What types of procedures take place at the establishment? | [ ]  Donor Selection [ ]  Consent[ ]  Preparing[ ]  Storage of bodies and/or body parts[ ]  Storage of former anatomical specimens[ ]  Transport[ ]  Import[ ]  Export |
| If human tissue will be distributed, please indicate to where distribution will occur | [ ]  Local [ ]  Regional [ ]  National [ ]  European Community [ ]  European Economic Area [ ]  Other international destination |

|  |  |
| --- | --- |
| How many staff members are involved in carrying out the licensable activity(ies) at the main site? |  |
| What organisations or private individuals, if any, are you holding samples on behalf of? (if applicable) |  |
| How many cadavers, on average, are accepted each year? |  |
| Please provide contact details of the proposed Persons Designated for the licence if the establishment is applying for a licence on one premises |  | Name | Job Title | Email | Telephone |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| To assist the Human Tissue Authority, please provide a synopsis describing:* The activities taking place
* How long the activities have been taking place
* How the facility is used
* How the facility is controlled
* How the facility relates or interacts with other establishments
 |
| How many adverse incidents have occurred in the establishment in the past 12 months? |  |
| Has the establishment previously been inspected by the HM Inspector of Anatomy (HMIA)? | Yes [ ]  No [ ] If so, please provide:Date of inspection:Recommendations resulting (if any): |

|  |
| --- |
| **Establishment Accreditation** |
| Does the establishment have any form of professional accreditation? (Such as CPA) | Yes [ ]  No [ ] If yes, please provide the following information for each accreditation:Accrediting body:Date accredited:Date enrolled:Awaiting assessment? Yes [ ]  No [ ] Approval date: |
| Any further information, such as explanation of the activities covered by the accreditations |  |

|  |
| --- |
| **Satellite Sites** |
| Does the establishment have any satellite sites? Yes ☐ No ☐If yes, please complete the below information for each satellite site. If you have more than two satellite sites you can copy and paste this part of the form onto a separate sheet. |
| **Satellite 1** Premises name:Address:Postcode:Activities undertaken at satellite:☐ Section 16(2)(a) - The carrying out of anatomical examination☐ Section 16(2)(c) - The removal of relevant material from the body of a deceased person of relevant material of which the body consists or which it contains for use of a Scheduled Purpose other than transplantation (where removal is not in the course of a post mortem examination)☐ Section 16(2)(d) - The storage of an anatomical specimen ☐ Section 16(2)(e)(i) and (ii) - 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, other than the storage of an anatomical specimen |
| Name of Person(s) Designated at the site | Job title | Email address | Telephone number |
| Primary: |  |  |  |
| Additional: |  |  |  |
| Additional: |  |  |  |
| When did the site become operational? (approximate date) |  |
| Please explain how the satellite site links to the governance of the hub  |  |

|  |  |
| --- | --- |
| To assist the Human Tissue Authority, please provide a short synopsis describing how the facility is used |  |
| Please explain what responsibilities the staff at the satellite site have for meeting the consent requirements of the Human Tissue Act and Codes of Practice |  |
| Does the satellite store relevant material on behalf of any organisation other than the hub?  | Yes [ ]  No [ ] If yes, please provide details. |
| Does the satellite supply or use relevant material for research purposes? | Yes [ ]  No [ ]  |
| Please state how many adverse events have occurred at the satellite in the last year |  |
| Does the satellite have any form of accreditation, such as CPA, MHRA, JACIE, ISO etc?  | Yes [ ]  No [ ] If yes, please provide the following information for each accreditation:Accrediting body:Date accreditation obtained:Current status: |
| Please provide any relevant further information |  |
| Name of person who completed this form (must be either the DI or LH from the hub): | Date: DD/MM/YYYY |

|  |
| --- |
| **Satellite 2**Premises name:Address:Postcode:Activities undertaken at satellite:[ ]  Section 16(2)(a) - The carrying out of anatomical examination[ ]  Section 16(2)(c) - The removal of relevant material from the body of a deceased person of relevant material of which the body consists or which it contains for use of a Scheduled Purpose other than transplantation (where removal is not in the course of a post mortem examination)[ ]  Section 16(2)(d) - The storage of an anatomical specimen [ ]  Section 16(2)(e)(i) and (ii) - 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, other than the storage of an anatomical specimen |
| Name of Persons Designated at the site | Job title | Email address | Telephone number |
| Primary: |  |  |  |
| Additional: |  |  |  |
| Additional: |  |  |  |
| When did the site become operational? (approximate date) |  |
| Please explain how the satellite site links to the governance of the hub  |  |
| To assist the Human Tissue Authority, please provide a short synopsis describing how the facility is used |  |

|  |  |
| --- | --- |
| Please explain what responsibilities the staff at the satellite site have for meeting the consent requirements of the Human Tissue Act and Codes of Practice |  |
| Does the satellite store relevant material on behalf of any organisation other than the hub?  | Yes [ ]  No [ ] If yes, please provide details. |
| Does the satellite supply or use relevant material for research purposes? | Yes [ ]  No [ ]  |
| Please state how many adverse events have occurred at the satellite in the last year |  |
| Does the satellite have any form of accreditation, such as CPA, MHRA, JACIE, ISO etc?  | Yes [ ]  No [ ] If yes, please provide the following information for each accreditation:Accrediting body:Date accreditation obtained:Current status: |
| Please provide any relevant further information |  |
| Name of person who completed this form (must be either the DI or LH from the hub): | Date: DD/MM/YYYY |

|  |
| --- |
| 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: [Designated Individuals and Licence Holders under the Human Tissue Act | Human Tissue Authority (hta.gov.uk)](https://www.hta.gov.uk/guidance-professionals/licensing/designated-individuals-and-licence-holders-under-human-tissue-act) |
| Title |  |
| Forenames |  |
| Surname |  |
| If you have been known by another name, please provide details |  |
| Correspondence address | Postcode: |
| Email |  |
| Telephone |  |
| Job title |  |
| Employer / parent organisation |  |
| 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 Individual** 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, 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 and confirm:a) I will follow the guidance set out in the Codes of Practice Yes ☐ No ☐produced by the HTA and as amended from time to time. 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 Yes ☐ No ☐to whom the licences apply are suitable persons to participate in the carrying out of the licensed activity(ies). d) I accept that I am responsible for securing that suitable Yes ☐ No ☐practices are used by the persons under my supervision in the course of carrying out the licensed activity(ies).e) I accept I am responsible for compliance with the conditions Yes ☐ No ☐of any licences granted.f) The information provided is true and accurate to the best of Yes ☐ No ☐ my knowledge.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 |  |
| If you have been known by another name, please provide details |  |
| Correspondence address | Postcode: |
| Email |  |
| Telephone |  |
| 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 LH |  |

|  |
| --- |
| **Declaration by proposed Licence Holder**Any 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 |

|  |
| --- |
| **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 |  |
| 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 Holder**Any 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 ☐c) I have been authorised to make this application on behalf Yes ☐ No ☐ of the applicant corporate body.Name: Date: DD/MM/YYYY |

**Human Tissue Authority Standards**

|  |
| --- |
| **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[ ]  Not met[ ]  Met |
| Please provide examples: |
| b) | Consent forms are available to those using or releasing relevant material for a scheduled purpose. | [ ]  Not applicable[ ]  Not met[ ]  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[ ]  Not met[ ]  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[ ]  Not met[ ]  Met |
| Please provide examples: |
| e) | Language translations are available when appropriate. | [ ]  Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |
| f) | Information is available in formats appropriate to the situation. | [ ]  Not applicable[ ]  Not met[ ]  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. | [ ] Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |
| b) | Records demonstrate up-to-date staff training. | [ ]  Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |
| c) | Competency is assessed and maintained. | [ ]  Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |

|  |
| --- |
| **Governance and Quality Systems** |
| **GQ1 – All aspects of the establishments 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[ ]  Not met[ ]  Met |
| Please provide examples: |
| b) | There is a document control system. | [ ]  Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |
| c) | There are change control mechanisms for the implementation of new operational procedures. | [ ]  Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |
| d) | Matters relating to HTA-licensable activities are discussed at regular governance meetings, involving establishment staff. | [ ]  Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |
| e) | There is a system for managing complaints. | [ ]  Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |

|  |
| --- |
| **GQ2 – There is a documented system of audit.** |
| 1. There is a documented schedule of audits ☐ Not applicable

 covering licensable activities. ☐ Not met ☐ Met |
| Please provide examples: |
| 1. There are documented induction training ☐ Not applicable

 programmes for new staff. ☐ Not met ☐ Met |
| Please provide examples: |

|  |
| --- |
| **GQ3 – Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.** |
| 1. Qualifications of staff and all training are recorded, ☐ Not applicable

 records showing attendance at training. ☐ Not met ☐ Met  |
| Please provide examples: |
| 1. There is documented induction training ☐ Not applicable

 programmes for new staff. ☐ Not met ☐ Met |
| Please provide examples: |
| c) Training provisions include those for visiting staff. ☐ Not applicable ☐ Not met ☐ Met |
| Please provide examples: |
| d) Staff have appraisals and personal development plans. ☐ Not applicable ☐ Not met ☐ Met |
| Please provide examples: |

|  |
| --- |
| **GQ4 – There is a systematic and planned approach to the management of records.** |
| 1. There are suitable systems for the creation, review, ☐ Not applicable

 amendment, retention and destruction of records. ☐ Not met ☐ Met |
| Please provide examples: |
| b) There are provisions for back-up / recovery in the ☐ Not applicable event of loss of records. ☐ Not met ☐ Met |
| Please provide examples: |
| c) Systems ensure data protection, confidentiality and ☐ Not applicable public disclosure (whistleblowing). ☐ Not met ☐ 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 ☐ Not applicable systems. ☐ Not met ☐ Met |
| Please provide examples: |
| 1. Effective corrective and preventive actions are ☐ Not applicable

taken where necessary and improvements in ☐ Not metpractice are made. ☐ Met |
| Please provide examples: |

|  |
| --- |
| **GQ6 – Risk assessments of the establishment’s practices and processes are****completed regularly, recorded and monitored.** |
| 1. There are documented risk assessments for ☐ Not applicable

all practices and processes requiring compliance ☐ Not metwith the HT Act and the HTA’s Codes of Practice. ☐ Met |
| Please provide examples: |
| b) Risk assessments are reviewed regularly. ☐ Not applicable  ☐ Not met ☐ Met |
| Please provide examples: |
| c) Staff can access risk assessments and are made ☐ Not applicableaware of risks during training. ☐ Not met ☐ Met |
| Please provide examples: |

|  |
| --- |
| **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[ ]  Not met[ ]  Met |
| Please provide examples: |
| b) | A register of donated material, and the associated products where relevant, is maintained. | [ ]  Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |
| c) | An audit trail is maintained, which includes details of when and where the bodies or tissue were acquired, the consent obtained, the uses to which any material was put, when and where the material was transferred, and to whom. | [ ]  Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |
| d) | A system is in place to ensure that traceability of relevant material is maintained during transport. | [ ]  Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |
| e) | Records of transportation and delivery are kept. | [ ] Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |
| f) | Records of any agreements with courier or transport companies are kept | [ ]  Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |
| g) | Records of any agreements with recipients of relevant material are kept. | [ ]  Not applicable[ ]  Not met[ ]  Met |
| Please provide examples: |

|  |
| --- |
| **T2 – Bodies and human tissue are disposed of in an appropriate manner.** |
| 1. Disposal is carried out in accordance with the [ ]  Not applicable

HTA’s Codes of Practice. [ ]  Not met [ ]  Met |
| Please provide examples: |
| b) The date, reason for disposal and the method [ ]  Not applicableused are documented. [ ]  Not met [ ]  Met |
| Please provide examples: |

|  |
| --- |
| Premises, Facilities and Equipment |
| **PFE1 – The premises are secure and fit for purpose.** |
| a) An assessment of the premises has been carried [ ]  Not applicableout to ensure that they are appropriate for the [ ]  Not metpurpose. [ ]  Met |
| Please provide examples: |
| b) Arrangements are in place to ensure that the [ ]  Not applicablepremises are secure and confidentiality is [ ]  Not metmaintained. [ ]  Met |
| Please provide examples: |
| c) There are documented cleaning and [ ]  Not applicabledecontamination procedures. [ ]  Not met [ ]  Met |
| Please provide examples: |

|  |
| --- |
| PFE2 – There are appropriate facilities for the storage of bodies and humantissue. |
| a) There is sufficient storage capacity. [ ]  Not applicable [ ]  Not met [ ]  Met |
| Please provide examples: |
| b) Storage arrangements ensure the dignity of the [ ]  Not applicabledeceased. [ ]  Not met [ ]  Met |
| Please provide examples: |
| c) Storage conditions are monitored, recorded and [ ]  Not applicableacted on when required. [ ]  Not met [ ]  Met |
| Please provide examples: |
| d) There are documented contingency plans in place [ ]  Not applicablein case of failure in storage area. [ ]  Not met [ ]  Met |
| Please provide examples: |

|  |
| --- |
| PFE3 – Equipment is appropriate for use, maintained, validated and whereappropriate monitored. |
| a) Equipment is subject to recommended [ ]  Not applicablecalibration, validation, maintenance, [ ]  Not metmonitoring, and records are kept. [ ]  Met |
| Please provide examples: |
| b) Users have access to instructions for equipment [ ]  Not applicableand are aware of how to report an equipment [ ]  Not metproblem. [ ]  Met |
| Please provide examples: |
| c) Staff are provided with suitable personal [ ]  Not applicableprotective equipment. [ ]  Not met [ ]  Met |
| Please provide examples: |

**Please submit the following documents as part of your application**

Please note that your application will not be processed unless you submit all of the below documents. If you are unable to provide any of the documents, please explain why below.

|  |
| --- |
| **Application Checklist – Mandatory documents** |
| **Consent** |
| [ ]  | Body donation consent form |
| [ ]  | Bequest booklet |
| **Governance and Quality Systems** |
| [ ]  | Organisational chart |
| [ ]  | Quality manual |
| [ ]  | Local code of conduct |
| [ ]  | List of SOPs of licensable activities (please note that these must be developed in line with guidance provided for standard GQ1) |
| [ ]  | Details of induction programme for new staff/training plan |
| [ ]  | List of organisations with TPA/SLA agreements in place for the provision of relevant material  |
| [ ]  | Adverse incidents policy/SOP |
| [ ]  | Risk assessments relevant to licensable activities (please note that these must be developed in line with the guidance provided in relation to standard GQ6 |
| **Traceability** |
| [ ]  | Disposal policy |
| [ ]  | Disposal SOP |
| **Premises, Facilities and Equipment** |
| [ ]  | Risk assessment of premises |
| [ ]  | Site plan, indicating where storage of relevant material will take place |
| [ ]  | Information on storage facilities that are/will be available (e.g. number of freezers, fridges, room temperature storage) |
| [ ]  | Contingency plan for failure in storage area |
| [ ]  | SOPs for monitoring and testing of storage conditions |

Further information on documentation:

|  |
| --- |
|  |