**Research Licence Application**

If you intend to store relevant material for use for a Scheduled Purpose, you can apply for a licence using this application form. Please do not use this application form if you plan to store anatomical specimens.

You can also use this form to apply for a licence to remove relevant material from the body of a deceased person for research.

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%20Research%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](mailto:licensing.enquiries@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 company  Company registration number:  Sole proprietor  Name and address:  Public Limited Company  Company registration number:  Charity  Charity registration number:  Partnership  Names and addresses of partners:  NHS Organisation  Please describe:  Other public body  Please describe:  Higher Education Institution  Other  Please 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)(e) (ii) - The storage of relevant material which has come from a human body for use for a scheduled purpose  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 | | | | | |
| Please provide names of the proposed Persons Designated for the licence if the establishment is applying for a licence on one premises | |  | Name | Job title | Email address | | Telephone |
| 1 |  |  |  | |  |
| 2 |  |  |  | |  |
| 3 |  |  |  | |  |
|  |  |  |  | |  |
| What body parts, tissues and/or cells will be collected or stored by the establishment? | | Surplus diagnostic material  Specific body parts, tissue or cell type(s)  If specific types, please provide the following information: | | | | | |
| Tissue collected | | | | Number in last 12 months | |
|  | | | |  | |
| Will you be storing material obtained from the living and/or the deceased? | | Living  Deceased | | | | | |

|  |  |
| --- | --- |
| How will the body parts, tissues and/or cells be stored? | Refrigerated  Frozen  Fixed and frozen  Fixed and stored at room temperature  Liquid nitrogen storage  Other – please describe: |
| What types of procedures will take place at the establishment? Please include approximately how many procedures will take place each year. | Donor selection – number:  Consent – number:  Procurement – number:  Storage – number:  Distribution – number:  Import – number:  Export – number: |
| If human tissue will be distributed, please indicate to where the distribution will occur | Local  Regional  National  European Community  European Economic Area (EEA) states  Other international destination(s) outside EEA  Other – please describe: |

|  |  |
| --- | --- |
| How many staff members will be involved in carrying out the licensable activity(ies) at the main site? |  |
| What organisations or individuals, if any, will you be holding samples on behalf of? |  |
| 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? |  |

|  |  |
| --- | --- |
| Establishment Accreditation | |
| Does the establishment have any form of professional accreditation? (Such as CPA) | Yes  No  If yes, please complete the questions below for each accreditation. Please continue on separate sheets if necessary. |
| Accrediting body:  Date accredited: DD/MM/YYYY Date enrolled: DD/MM/YYYY  Awaiting assessment? Yes  No  Conditional approval date: DD/MM/YYYY  Any further information, such as explanation of the activities covered by the accreditations: | |
| Accrediting body:  Date accredited: DD/MM/YYYY Date enrolled: DD/MM/YYYY  Awaiting assessment? Yes  No  Conditional approval date: DD/MM/YYYY  Any further information, such as explanation of the activities covered by the accreditations: | |
| Accrediting body:  Date accredited: DD/MM/YYYY Date enrolled: DD/MM/YYYY  Awaiting assessment? Yes  No  Conditional approval date: DD/MM/YYYY  Any further information, such as explanation of the activities covered by the accreditations: | |
| Accrediting body:  Date accredited: DD/MM/YYYY Date enrolled: DD/MM/YYYY  Awaiting assessment? Yes  No  Conditional approval date: DD/MM/YYYY  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)(e) (ii) - The storage of relevant material which has come from a human body for use for a scheduled purpose  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 | | | | | |
| 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)(e) (ii) - The storage of relevant material which has come from a human body for use for a scheduled purpose  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 | | | | | |
| 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 | |

|  |  |
| --- | --- |
| **Application to be Designated Individual (DI)**  To be completed by proposed DI  Before 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 |  |
| 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 produced by the HTA 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 |  |
| 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 Licence Holder |  |

|  |  |
| --- | --- |
| **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 corporate body and relevant details | Limited company  Company registration number:  Sole proprietor  Name and address:  Public Limited Company  Company registration number:  Charity  Charity registration number:  Partnership  Names and addresses of partners:  NHS Organisation  Please describe:  Other public body  Please describe:  Higher Education Institution  Other  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 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 of the applicant corporate body. | | Yes  No |
| 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, which addresses the requirements of the HT Act and the HTA’s Codes of Practice. | 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-licensed 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.** | | |
| a) | There is a documented schedule of audits covering licensable activities. | Not applicable  Not met  Met |
| Please provide examples: | | |
| b) | Audit findings include who is responsible for follow-up actions and the timeframes for completing these. | Not applicable  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.** | | |
| a) | Qualifications of staff and all training are recorded, records showing attendance at training. | Not applicable  Not met  Met |
| Please provide examples: | | |
| b) | There are documented induction training programmes for new staff. | Not applicable  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.** | | |
| a) | There are suitable systems for the creation, review, amendment, retention and destruction of records. | Not applicable  Not met  Met |
| Please provide examples: | | |
| b) | There are provisions for back-up / recovery in the event of loss of records. | Not applicable  Not met  Met |
| Please provide examples: | | |
| c) | Systems ensure data protection, confidentiality and public disclosure (whistleblowing). | Not applicable  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 systems. | Not applicable  Not met  Met |
| Please provide examples: | | |
| b) | Effective corrective and preventive actions are taken where necessary and improvements in practice are made. | Not applicable  Not met  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  Not met  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 aware of risks during training. | Not applicable  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 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  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.** | | |
| a) | Disposal is carried out in accordance with the HTA’s Codes of Practice. | Not applicable  Not met  Met |
| Please provide examples: | | |
| b) | The date, reason for disposal and the method used are documented. | Not applicable  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 out to ensure that they are appropriate for the purpose. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| b) | Arrangements are in place to ensure that the premises are secure and confidentiality is maintained. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| c) | There are documented cleaning and decontamination procedures. | Not applicable  Not met  Met | |
| Please provide examples: | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **PFE2 – There are appropriate facilities for the storage of bodies and human**  **tissue.** | | | |
| a) | There is sufficient storage capacity. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| b) | Where relevant, storage arrangements ensure the dignity of the deceased. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| c) | Storage conditions are monitored, recorded and acted on when required. | Not applicable  Not met  Met | |
| Please provide examples: | | | |
| d) | There are documented contingency plans in place in case of failure in storage area. | Not applicable  Not met  Me | |
| Please provide examples: | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **PFE3 – 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  Not met  Met |
| Please provide examples: | | | |
| b) | Users have access to instructions for equipment and are aware of how to report an equipment problem. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| c) | Staff are provided with suitable personal protective equipment. | Not applicable  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 above documents. If you are unable to provide any of the documents, please explain why below.

|  |  |
| --- | --- |
| **Application Checklist – Mandatory documents** | |
| **Consent** | |
|  | Consent form |
|  | Patient information sheet on consent (or equivalent) |
| **Governance and Quality Systems** | |
|  | Organisational chart |
|  | Quality manual |
|  | 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 for activities related to the licence (for example consent, sample management and storage, traceability, disposal) |
|  | A copy of the Adverse incidents policy and SOP |
|  | A copy of the SOP covering traceability of relevant material |
|  | A copy of all 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 |
| **Premises, Facilities and Equipment** | |
|  | Risk assessment of premises |
|  | List of critical facilities, equipment, materials and reagents |
|  | 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

|  |
| --- |
|  |