

# Application form for a Licence under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended)

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| **Establishment Information**  |
| Full name of organisation |  |
| Department (if applicable) |  |
| Address | Postcode: |
| Activities to be licensed under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended)  | **Procurement activities**[ ]  Donor characterisation[ ]  Organ characterisation[ ]  Preservation of an organ[ ]  Making arrangements to transport an organ[ ]  Retrieval of an organ**Transplantation activities**[ ]  Organ characterisation[ ]  Preservation of an organ[ ]  Making arrangements to transport an organ[ ]  Implantation of an organ |
| Which organs (or composite tissue types) are retrieved and/or implanted? | Organ/composite tissue type (continue on separate sheet if necessary) |
| 1. |
| 2. |
| 3. |
| 4. |
| 5. |
| 6. |

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| **To assist the Human Tissue Authority, please provide a synopsis of the activities to be covered by the licence:** |
| **Named Contacts** |
| Please provide details of named contacts working under the licence | **Person 1** |
| Title |  |
| Name |  |
| Job title |  |
| Telephone number |  |
| Email address |  |
|  |  |
| **Person 2** |
| Title |  |
| Name |  |
| Job title |  |
| Telephone number |  |
| Email address |  |
|  |
| **Person 3** |
| Title |  |
| Name |  |
| Job title |  |
| Telephone number |  |
| Email address |  |
|  |  |
| **Person 4** |  |
| Title |  |
| Name |  |
| Job title |  |
| Telephone number |  |
| Email address |  |
|  |
| **Person 5** |
| Title |  |
| Name |  |
| Job title |  |
| Telephone number |  |
| Email address |  |
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| **Details of Retrieval Teams who will be working under the Licence** |
| Retrieval team |  |
| Employing body or organisation |  |
| Retrieval team specialism | [ ]  Cardiothoracic [ ]  Abdominal[ ]  Other – please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| Retrieval team  |  |
| Employing body or organisation |  |
| Retrieval team specialism | [ ]  Cardiothoracic [ ]  Abdominal[ ]  Other – please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |
| Retrieval team  |  |
| Employing body or organisation |  |
| Retrieval team specialism | [ ]  Cardiothoracic [ ]  Abdominal[ ]  Other – please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Application to be Corporate Licence Holder (CLH)** |
| Full name of corporate body |  |
| Address | Postcode: |
| Type of corporate body | [ ]  Limited company[ ]  NHS organisation[ ]  Other – please describe \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Contact details for Licence Holder or person authorised to sign on behalf of the Licence Holder / Corporate Body** |
| Title |  |
| Forename(s) |  |
| Surname |  |
| Job title |  |
| Email address |  |
| Telephone number |  |
| Mobile phone number |  |

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| **Declaration by Licence Holder applicant** Any person completing this application 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 or misleading.I confirm I understand the conditions and directions under which a licence will be granted under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) and confirm: |
| a) The information provided is true and accurate to the best of my knowledge and belief. | Yes [ ]  No [ ]  |
| b) I have been authorised to make this application on behalf of the Licence Holder. | Yes [ ]  No [ ]  |
| c) I confirm that the Licence Holder will comply with any Directions issued by the Human Tissue Authority. | Yes [ ]  No [ ]  |
| d) I confirm the Licence Holder has read and understood the Human Tissue Authority documentary framework.  | Yes [ ]  No [ ]  |
| e) I confirm the Licence Holder will meet the Directions laid down by the Human Tissue Authority in the documentary framework. | Yes [ ]  No [ ]  |
| f) I confirm the Licence Holder will pay fees as required for a licence by the Human Tissue Authority. | Yes [ ]  No [ ]  |
| g) I confirm the Licence Holder understands there is a legal duty to secure compliance with the conditions of the licence and with the Directions given by the Human Tissue Authority. | Yes [ ]  No [ ]  |
| h) I confirm the Licence Holder understands that the Human Tissue Authority will conduct an audit to ensure compliance with the licence conditions from time to time. The Licence Holder will assist the Human Tissue Authority in this audit. | Yes [ ]  No [ ]  |
| i) Consent or authorisation requirements for organ donation for transplantation are obtained or verified in accordance with relevant legislation. | Yes [ ]  No [ ]  N/A [ ]  |
| Name: | Date: DD/MM/YYYY |

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| **Assessment Criteria for compliance with the requirements of the** **Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended)****Some conditions apply to all licensed activities, whereas other conditions apply to different licensed activities, and these are marked in the box to the right. Please complete each relevant section and, where compliance is anything other than ‘Fully met’, explain why and what action is being taken to meet the criteria in full.** |
| **General** |
| **Assessment Criteria** | **Compliance** | **Licensed Activity** |
| Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are competent and suitably qualified or trained to perform their tasks. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met |  All |
| Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are provided with the training necessary to perform their tasks. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met |  All |
| Medical activities are performed under the advice and guidance of a registered medical practitioner, and there are operating procedures in place to demonstrate this. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met | All |
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| **Donor and organ characterisation** |
| Where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | DCOC |
| Donors and organs are characterised before implantation by the collection of information specified in Annex A of The Quality and Safety of Organs Intended for Transplantation: A documentary framework. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | DCOC |
| Donors and organs are characterised before implantation by, where considered appropriate, the collection of information specified in Annex B of The Quality and Safety of Organs Intended for Transplantation: A documentary framework. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | DCOC |
| All information relating to donor and organ characterisation is kept for a period of 30 years from the date of retrieval of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | DCOC |
| Tests required for donor and organ characterisation are carried out by laboratories with United Kingdom Accreditation Service (UKAS) accreditation (to ISO15189:2012). | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | DCOC |
| Information on organ and donor characterisation reaches the person who will be implanting an organ within a time period that would not compromise the quality and safety of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | DCOC |
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| **Retrieval of organs for transplantation** |
| Procurement is only carried out after all the requirements relating to consent (or authorisation in Scotland) have been met. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | R |
| Material and equipment used in retrieval meets the requirements of The Medical Devices Regulations 2002 (SI 2002/618) (as amended) (UK MDR 2002), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | R |
| Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | R |
| Endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | R |

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| **Organ preservation** |
| Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618) (as amended) (UK MDR 2002), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | P |
| Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | P |
| Records of perfusion fluid coming into contact with organs contain the identity of the fluid, including the manufacturer; batch number and expiry date, and are kept for a period of 30 years from the date of retrieval of the organ. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | P |
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| **Making arrangements for the transportation of organs** |
| The integrity of the organ is maintained during transport and the transport time is suitable to ensure the quality and safety of the organ, and there is an operating procedure in place to demonstrate how this requirement is complied with. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | T |
| The organ shipping container is suitable for transport of the specified organ. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | T |

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| The organ shipping container used for transporting organs from the licensed premises is labelled with the information specified in The Quality and Safety of Organs Intended for Transplantation: A documentary framework, and there is an operating procedure in place to demonstrate how this requirement is complied with. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | T |
| Transported organs are accompanied by a report on the organ and donor characterisation, and there is an operating procedure in place to demonstrate how this requirement is complied with. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | T |
| Arrangements are in place to ensure that any organisations transporting organs on behalf of the licence holder meet the requirements for transportation and serious adverse event and reaction reporting specified in the framework document. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | T |
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| **Implantation** |
| The identification of the donor and the collection of the information in Annex A and B of The Quality and Safety of Organs Intended for Transplantation: A documentary framework, are verified prior to proceeding to implant an organ, and there is an operating procedure in place to demonstrate how this requirement is complied with. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | I |
| Compliance with the conditions of preservation and transport outlined in The Quality and Safety of Organs Intended for Transplantation: A documentary framework are verified prior to proceeding to implant an organ. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | I |
| Where any of the information specified in Annex A of The Quality and Safety of Organs Intended for Transplantation: A documentary framework is not available, a risk-benefit analysis is conducted to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | I |
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| **Traceability** |
| The data required to ensure traceability of organs is recorded using the HTA A and B forms, which are returned to NHSBT within 7 days, and there is an operating procedure in place to demonstrate how this requirement is complied with. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | All |
| There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | All |
| A record (date and time) of the transportation of organs arriving at and/or leaving the establishment is kept for 30 years as part of the traceability information. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | All |

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| **Serious Adverse Events and Serious Adverse Reactions (SAEARs)** |
| Operating procedures are in place for the management of a serious adverse event or a serious adverse reaction. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | All |
| Serious adverse events and reactions are reported to NHSBT within 24 hours of discovery, a follow-up report is provided within 90 days, and there is an operating procedure in place to demonstrate how this requirement is complied with. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | All |
| Third parties, such as those undertaking testing or transportation, are instructed to report any serious adverse events and reactions to the licence holder within 24 hours of discovery or determination. | [ ]  Not applicable[ ]  Not met[ ]  Partially met[ ]  Almost met[ ]  Fully met  | All |

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