HTA Human Application sector licence application form

Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), no person shall store or import tissue or cells intended for human application otherwise than under the authority of an appropriate HTA licence.

Furthermore, under this legislation, no person shall procure, process, distribute, or export tissues or cells intended for human application, or carry out related donor serology testing, unless under the authority of an appropriate HTA licence or in pursuance of a third party agreement with an appropriately licensed establishment.

Please use this form to apply for a licence to carry out such activities.

If you are completing this application on behalf of:

* an establishment based in Northern Ireland (NI) applying for a licence to import tissues and cells for human application from a supplier based in Great Britain (GB); or,
* an establishment based in GB applying for a licence to import or export tissues and cells for human application from/to the European Economic Area (EEA)

please contact the HTA at [licensing.enquiries@hta.gov.uk](mailto:licensing.enquiries@hta.gov.uk) to ensure you are completing the correct application form.

**Links to further information**

Please refer to the [HTA’s website](https://www.hta.gov.uk) for:

* [information about HTA licensing](https://www.hta.gov.uk/guidance-professionals/licensing/licensing-under-human-tissue-quality-and-safety-human-application);
* the [HTA Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment](https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance), which explains the regulatory requirements for establishments in the Human Application sector; and,
* [information on the role and responsibilities of Designated Individuals and Licence Holders](https://www.hta.gov.uk/guidance-professionals/licensing/designated-individuals-and-licence-holders-under-human-tissue) under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as amended (the Q&S Regulations)

Please contact us at [licensing.enquiries@hta.gov.uk](mailto:licensing.enquiries@hta.gov.uk) if you have any questions about your application.

**1: Establishment Information**

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| Part 1: 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 additional 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 to replace an existing licence?** | | Yes  No  If yes, please state the existing licence number you are applying to replace: | | | | |
| **Activities to be licensed under the Human Tissue Act 2004** | | The storage of relevant material which has come from a human body, for use for Scheduled Purposes other than transplantation under the Human Tissue Act 2004 | | | | |
| **Activities to be licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)** | | Procurement  Testing  Processing - If you are applying for a licence in order to be able to process tissue or cells for human application, please also [complete a Preparation Process Dossier](https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/preparation-process-dossiers-guidance).  Storage  Distribution  Import  Export | | | | |
| **Will the establishment be responsible for donor selection?** | | Yes  No | | | | |
| **Will the establishment be responsible for obtaining consent?** | | Yes  No | | | | |
| **Will the establishment be an end user of the tissue and/or cells?** | | Yes  No | | | | |
| **Distribution** | | Local  Regional  National  International destination(s)  Other – please describe: | | | | |
| **How many staff members will be involved in carrying out the licensable activity(ies) at the main site?** | |  | | | | |
| **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 |
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| 3 |  |  |  |  |
| **What tissues and/or cells will be procured, tested, processed, stored, distributed, imported and exported?** | |  | | | | |
| **For each tissue or cell type please state how many units on average will be procured, tested, processed, stored distributed and imported/exported each year.**  **Please continue on separate sheets if necessary.** | | **Tissue type:** | | **Usage:** | **Average number of units:** | |
|  | | Procured |  | |
| Processed |  | |
| Stored |  | |
| Distributed |  | |
| Imported |  | |
| Exported |  | |
| Tested |  | |
|  | | Procured |  | |
| Processed |  | |
| Stored |  | |
| Distributed |  | |
| Imported |  | |
| Exported |  | |
| Tested |  | |
|  | | Procured |  | |
| Processed |  | |
| Stored |  | |
| Distributed |  | |
| Imported |  | |
| Exported |  | |
| Tested |  | |
|  | | Procured |  | |
| Processed |  | |
| Stored |  | |
| Distributed |  | |
| Imported |  | |
| Exported |  | |
| Tested |  | |
| To assist the Human Tissue Authority, please provide a synopsis describing:   * The activities that will take place * How the facility will be used * How the facility will be controlled * How the facility will relate or interact with other establishments | | | | | | |
| **Will you be storing relevant material for research?** | | Yes  No  If yes, please provide a brief synopsis of what material will be stored, the quantity and who will be using the material.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |

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| Part 2: Establishment Accreditations | |
| Does the establishment have any form of professional accreditation? | 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: | |

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| Part 3: [Satellite Sites](http://www.hta.gov.uk/licensingandinspections/satellitepremises.cfm) | | | | | | | | |
| Will 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. | | | | | | | | |
| 3.1 Satellite 1 | | | | | | | | |
| **Premises name** |  | | | | | | | |
| **Address where licensed activity is to take place** |  | | | | | | | |
| **Postcode** |  | | | | | | | |
| **Activity(ies) to be licensed at the satellite site**  Please note these activities must be included on the licence for the hub. | | | | | | | | |
| Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) | | | Procurement  Testing  Processing  Storage  Distribution  Import  Export | | | | | |
| Under the Human Tissue Act 2004 | | | Section 16(2)(e) (ii) – The storage of relevant material which has come from a human body 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 will the site become operational? (approximate date)** | |  | | | | | | |
| **Will the satellite be under the same governance as the main hub?** | | Yes  No | | | | | | |
| **Please explain how the satellite site will link to the governance of the hub** | |  | | | | | | |
| **To assist the Human Tissue Authority, please provide a short synopsis describing the activities that will be carried out at the satellite on behalf of the establishment** | |  | | | | | | |
| **How will the DI supervise the activities at the satellite site?** | |  | | | | | | |
| **How many staff will be involved in carrying out the licensable activity at the satellite site?** | |  | | | | | | |
| **Please explain what responsibilities the staff at the satellite site will have for meeting the consent requirements of the Human Tissue Act and Codes of Practice** | |  | | | | | | |
| **Will the satellite store relevant material on behalf of any organisation other than the hub?** | | Yes  No  N/A  If yes, please provide details. | | | | | | |
| **Will the satellite supply or use relevant material for research purposes?** | | Yes  No | | | | | | |
| **Does the satellite have any form of accreditation, such as MHRA, JACIE, ISO etc?** | | Yes  No  If yes, please provide the following information for each accreditation:  Accrediting body:  Date accreditation obtained:  Current status:  Any further information: | | | | | | |
| **For each tissue type please state how many units on average will be procured, processed, stored, distributed and imported / exported by the satellite each year.**  **Please continue on a separate sheet if necessary.** | | **Tissue type** | | | | **Usage** | **Average number of units** | |
|  | | | | Procured |  | |
| Tested |  | |
| Processed |  | |
| Stored |  | |
| Distributed |  | |
| Imported |  | |
| Exported |  | |
|  | | | | Procured |  | |
| Tested |  | |
| Processed |  | |
| Stored |  | |
| Distributed |  | |
| Imported |  | |
| Exported |  | |
|  | | | | Procured |  | |
| Tested |  | |
| Processed |  | |
| Stored |  | |
| Distributed |  | |
| Imported |  | |
| Exported |  | |
| **Please provide any additional information you feel may be relevant to this application** |  | | | | | | | |
| 3.2 Satellite 2 | | | | | | | | |
| **Premises name** |  | | | | | | | |
| **Address where licensed activity is to take place** |  | | | | | | | |
| **Postcode** |  | | | | | | | |
| **Activity(ies) to be licensed at the satellite site**  Please note these activities must be included on the licence for the hub. | | | | | | | | |
| Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) | | | Procurement  Testing  Processing  Storage  Distribution  Import  Export | | | | | |
| Under the Human Tissue Act 2004 | | | Section 16(2)(e) (ii) – The storage of relevant material which has come from a human body 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 will the site become operational? (approximate date)** | |  | | | | | | |
| **Will the satellite be under the same governance as the main hub?** | | Yes  No | | | | | | |
| **Please explain how the satellite site will link to the governance of the hub** | |  | | | | | | |
| **To assist the Human Tissue Authority, please provide a short synopsis describing the activities that will be carried out at the satellite on behalf of the establishment** | |  | | | | | | |
| **How will the DI supervise the activities at the satellite site?** | |  | | | | | | |
| **How many staff will be involved in carrying out the licensable activity at the satellite site?** | |  | | | | | | |
| **Please explain what responsibilities the staff at the satellite site will have for meeting the consent requirements of the Human Tissue Act and Codes of Practice** | |  | | | | | | |
| **Will the satellite store relevant material on behalf of any organisation other than the hub?** | | Yes  No  N/A  If yes, please provide details. | | | | | | |
| **Will the satellite supply or use relevant material for research purposes?** | | Yes  No | | | | | | |
| **Does the satellite have any form of accreditation, such as MHRA, JACIE, ISO etc?** | | Yes  No  If yes, please provide the following information for each accreditation:  Accrediting body:  Date accreditation obtained:  Current status:  Any further information: | | | | | | |
| **For each tissue type please state how many units on average will be procured, processed, stored, distributed and imported / exported by the satellite each year.**  **Please continue on a separate sheet if necessary.** | | **Tissue type:** | | | | **Usage:** | **Average number of units:** | |
|  | | | | Procured |  | |
| Tested |  | |
| Processed |  | |
| Stored |  | |
| Distributed |  | |
| Imported |  | |
| Exported |  | |
|  | | | | Procured |  | |
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|  | | | | Procured |  | |
| Tested |  | |
| Processed |  | |
| Stored |  | |
| Distributed |  | |
| Imported |  | |
| Exported |  | |
| **Please provide any additional information you feel may be relevant to this application** |  | | | | | | | |

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| Part 4: Third Party Information |
| To be completed by proposed Designated Individual for each third-party agreement. |
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| Part 5: Third Country Supplier (3CS) Information | | | | | |
| To be completed if you propose to import:   * human tissue or cells to be used for human application or as the starting material in the manufacture of an Advanced Therapy Medicinal Product (ATMP); or * products derived from human tissues/cells.   To be completed for each 3CS.  **If you are based in GB and intend to import from suppliers in the European Economic Area (EEA) only, or you are based in NI and wish to import from suppliers based in GB, please contact us to discuss your application and confirm you are completing the correct form.** | | | | | |
| **Complete and return this spreadsheet with your application:** |  | | | | |
| **Is there an agreement in place with the third party covering the requirements set out in** [**paragraph 255 of the Guide**](https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance)**?** | Yes  No  Agreement start date:  Agreement end date (if applicable): | | | | |
| **How often will the agreement be reviewed?** |  | | | | |
| **Name of the site of reception for imports (if different to licensed establishment)** |  | | | | |
| **Address of the site of reception for imports (if different or in addition to licensed establishment)** |  | | | | |
| **Brief synopsis of proposed import activity** |  | | | | |
| **Do you require a licence for routine or one-off import activities?** | Routine  Complete section 5.1 | | One-off  Complete section 5.2 | Both  Complete sections 5.1 and 5.2 | |
| 5.1 3CS Information  The importing tissue establishment (ITE) is responsible for ensuring the quality and safety of the tissues and cells they import meet standards equivalent to the ones laid down in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended).  Complete the following self assessment against the documentary requirements set out in paragraphs 252-255 of the [HTA Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment](https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance).  To be completed for each 3CS. Information can be appended to the application if needed. | | | | | | |
| **Do you have** | | **Availability to ITE** | | | **Verified against the requirements of Directions 001/2021** | |
| Detailed information on:the criteria used for donor identification and evaluationinformation provided to the donor or donor familyhow consent is obtained from the donor or donor’s family | | Not applicable  Yes  No  If no, provide details of information held by the ITE: | | | Not applicable  Yes  No | |
| For each tissue type or product, will the donation be voluntary and unpaid? | | Yes  No  Don’t know | | |  | |
| Detailed information on the testing centre(s) used by the 3CS and the tests performed, including documentation relating to the validation of the tests and timing of blood samples taken for donor serology testing | | Not applicable  Yes  No  If no, provide details of information held by the ITE: | | | Not applicable  Yes  No | |
| Detailed information on the methods used during processing of the tissues / cells, including details of the validation work that has been performed | | Not applicable  Yes  No  If no, provide details of information held by the ITE: | | | Not applicable  Yes  No | |
| **Where tissues and cells for human application are processed before receipt by the ITE without a subsequent validated microbial inactivation or terminal sterilisation process, do you have details of the environmental monitoring carried out during critical processing? \*** | | Not applicable  Yes  No  Please provide details of the environmental monitoring carried out during critical processing: | | | Not applicable  Yes  No | |
| For each activity carried out prior to import, do you have:  * **a detailed description of the facility in which the activity is carried out** * **a list of all critical equipment used** * **a list of all materials used** | | Not applicable  Yes  No  If no for any requirement, provide details of information held by the ITE: | | | Not applicable  Yes  No | |
| **For each activity carried out prior to import, do you have a list of all relevant quality control criteria?** | | Yes  No  If no, provide details of information held by the ITE: | | | Yes  No | |
| **For each activity carried out prior to import, will you have details of the conditions for release?** | | Yes  No  If no, provide details of information held by the ITE: | | | Yes  No | |
| **A summary of the most recent inspection of the 3CS by the third country competent authority or authorities, including the date of the inspection, type of inspection and main conclusions** | | Not applicable  Yes  No  If no, provide details of information held by the ITE: | | | Not applicable  Yes  No | |
| A summary of the most recent audit of the 3CS carried out by, or on behalf of, the ITE | | Not applicable  Yes  No  If no, provide details of information held by the ITE: | | | Not applicable  Yes  No | |
| Any relevant national or international accreditation | | Not applicable  Yes  No  If no, provide details of information held by the ITE: | | | Not applicable  Yes  No | |

\* For example, whenever tissues/cells are exposed to the environment during processing and the processing step is not followed by a validated microbial inactivation or validated terminal sterilisation process, are the following forms of environmental monitoring carried out for the full duration of critical processing:

1. the use of settle plates;

2. the use of finger dabs of the operator following processing; and

3. the use of non-viable particle monitoring during open processing.

Please also indicate whether these strategies are employed for the duration of each open processing event or on a scheduled basis.

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| 5.2 One-Off Imports: Required Information  To be completed by the proposed Designated Individual for each 3CS supplier. | | | |
| **What tissues / cells do you require one-off import authorisation for?** | |  | |
| **Will the tissues / cells be for autologous or allogeneic use?** | |  | |
| **Will the cells be used for immediate transplantation?** | |  | |
| **Will the imported tissues / cells be for a named recipient, known to the importer and 3CS before import?** | |  | |
| **Do you intend to use the same 3CS more than once?** | |  | |
| **Do you have an approved 3CS for this tissue type?** | |  | |
| **What activities will be carried out by the 3CS before import?** | |  | |
| **How will you select an appropriate 3CS for one-off import?** | |  | |
| **How will you ensure that imported tissues / cells have standards of quality and safety equivalent to those described in Directions 001/2021?** | |  | |
| **How will you ensure that traceability will be maintained?** | |  | |
| **How will you ensure that imported tissues / cells are not used in anyone other than their intended recipients?** | |  | |
| Part 6: Application to be [Designated Individual](http://www.hta.gov.uk/licensingandinspections/peopleatlicensedestablishments/disandlicenceholdersundertheq&sregulations.cfm) (DI) | | | |
| To be completed by proposed DI.  Before completing, we recommend you read the [useful information for DIs](https://www.hta.gov.uk/guidance-professionals/licensing/designated-individuals-and-licence-holders-under-human-tissue) we have published on our website. | | | |
| **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 (please include details of any diploma, certificate or degree or other evidence of formal qualifications in the fields of medicine or biological science and any other academic qualifications)** |  | | |
| **Membership of relevant professional bodies and registration numbers where applicable** |  | | |
| **Details of any other relevant experience, including practical experience in the fields of medicine, biological science, 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 or misleading.  I understand the terms and conditions under which a licence will be granted under the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), particularly my duties under Section 18 of the Act and Regulation 12 of the Regulations 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 activity(ies) 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 activity(ies). | | | 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 activity(ies). | | | Yes  No |
| e) I accept I am responsible for compliance with the conditions of any licence(s) granted. | | | Yes  No |
| f) I accept that I, the Licence Holder and the establishment must comply with any Directions issued by the Human Tissue Authority from time to time. | | | Yes  No |
| g) I acknowledge that the requirements of any Directions issued by the Human Tissue Authority from time to time represent suitable practices in the course of carrying on the licensed activity(ies). | | | Yes  No |
| h) I accept that I am responsible for compliance with the conditions of any and all third-party agreements entered into by or on behalf of the Licence Holder in relation to the licensed activity(ies) authorised to be carried out under my supervision. | | | Yes  No |
| i) I accept that I am responsible for securing compliance with the requirements of Regulation 13(1) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) regarding information and confidentiality. | | | Yes  No |
| j) The information provided is true and accurate to the best of my knowledge. | | | Yes  No |
| k) I consent to be the Designated Individual for the licence application made by the proposed Licence Holder and, where applicable, consent to be the Licence Holder. | | | Yes  No |
| Name: | | | Date: DD/MM/YYYY |

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| Part 7: Application to be Individual [Licence Holder](http://www.hta.gov.uk/licensingandinspections/peopleatlicensedestablishments/disandlicenceholdersundertheq&sregulations.cfm) (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** |  | |
| **Email** |  | |
| **Telephone** |  | |
| **Fax** |  | |
| **Correspondence address if different from licensed premises** | Postcode: | |
| **Job title** |  | |
| **Employing body or organisation** |  | |
| **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 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 or misleading.  I understand the terms and conditions under which a licence will be granted under the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) 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 accept that the Licence Holder is responsible under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) for entering into third party agreements with any third parties that procure, test, process, distribute or export tissues and/or cells for human application on behalf of the establishment, or supply any goods or services which may affect the quality or safety of tissues and/or cells. | | Yes  No |
| d) I accept that I, the Designated Individual and the establishment must comply with any Directions issued by the Human Tissue Authority from time to time. | | Yes  No |
| e) I acknowledge that the requirements of any Directions issued by the Authority from time to time represent suitable practices in the course of carrying out licensed activity(ies) | | Yes  No |
| Signature: | | Date: DD/MM/YYYY |

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| Part 8: Application to be Corporate [Licence Holder](http://www.hta.gov.uk/licensingandinspections/peopleatlicensedestablishments/disandlicenceholdersundertheq&sregulations.cfm) (LH)  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. | | |
| **Full name of 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** |  | |
| **Name, job title and qualifications of person completing this application on behalf of the corporate body (and therefore authorised to sign on behalf of the corporate body)** | Name:  Job title:  Qualifications: | |
| **Correspondence address if different from the licensed premises** |  | |
| **Email** |  | |
| **Telephone** |  | |
| **Please explain why the corporate body is suitable for the role of the LH** |  | |
| Declaration by proposed Corporate Licence Holder 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 or misleading.  On behalf of the corporate body I accept the terms and conditions under which a licence will be granted under the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) 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 |
| d) I accept that the Licence Holder is responsible under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) for entering into third party agreements with any third parties that procure, test, process, distribute or export tissues and/or cells for human application on behalf of the establishment, or supply any goods or services which may affect the quality or safety of tissues and/or cells. | | Yes  No |
| e) I accept that the Licence Holder, the Designated Individual and the establishment must comply with any Directions issued by the Human Tissue Authority from time to time. | | Yes  No |
| f) I, on behalf of the Licence Holder, acknowledge that the requirements of any Directions issued by the Human Tissue Authority from time to time represent suitable practices in the course of carrying on the licensed activity(ies). | | Yes  No |
|  | |  |
| Signature: | | Date: DD/MM/YYYY |

Part 9: Human Tissue Authority [Standards](http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm)

This section lists all the licensing standards in the HA sector. Please complete each section applicable to the activities you are applying to hold a licence for. Provide examples below each standard to evidence your establishment’s compliance with that standard.

If the standard is only partially met or not met, explain why and what action is being taken at your establishment to meet the standard in full.

|  |  |  |  |
| --- | --- | --- | --- |
| Consent | | | |
| C1 | Consent is obtained in accordance with the requirements of the Human Tissue Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and as set out in the Human Tissue Authority Codes of Practice. | | |
| C1a | If the establishment acts as a procurer of tissues and/or cells, there is an established process for acquiring donor consent which meets the requirements of the Human Tissue Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and the HTA’s Codes of Practice. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| C1b | If there is a third party procuring tissues and/or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the Human Tissue Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and the HTA’s Codes of Practice. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| C1c | The establishment or the third party’s procedure on obtaining donor consent includes how potential donors are identified and who can take consent. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| C1d | Consent forms comply with the HTA Codes of Practice. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| C1e | Completed consent forms are included in records and are made accessible to those using or releasing tissue and /or cells for a Scheduled Purpose. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| C2 | Information about the consent process is provided and in a variety of formats. | | |
| C2a | The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 001/2021 is included. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| C2b | If third parties act as procurers of tissues and/or cells, the third-party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 001/2021 is included. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| C2c | Information is available in suitable formats and there is access to independent interpreters when required. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| C2d | There are procedures to ensure that information is provided to the donor or donor ‘s family by trained personnel. | | Not applicable  Not met  Met |
| Please provide examples: | | | |
| C3 | | Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent. | |
| C3a | | Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent. | Not applicable  Not met  Met |
| Please provide examples: | | | |
| C3b | | Training records are kept demonstrating attendance at training on consent | Not applicable  Not met  Met |
| Please provide examples: | | | |

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| --- | --- | --- | --- | --- |
| Governance and Quality Systems | | | | |
| GQ1 | All aspects of the establishment’s work are supported by ratified documented policies and procedures as part of the overall governance process. | | | |
| GQ1a | There is an organisational chart clearly defining the lines of accountability and reporting relationships. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1b | There are procedures for all licensable activities that ensure integrity of tissue and/or cells and minimise the risk of contamination. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1c | There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1d | There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1e | There are procedures for tissue and/or cell procurement, which ensure the safety of living donors. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1f | There are procedures for tissue and /or cell procurement, which ensure the dignity of deceased donors. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1g | There are procedures to ensure that an authorised person verifies that tissues and/or cells received by the establishment meet required specifications. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1h | There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1i | There are procedures to ensure tissues and /or cells are not released from quarantine until verification has been completed and recorded. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1j | There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the Medical Devices Regulation 2002 (SI 2002 618, as amended) (UK MDR 2002) and United Kingdom Conformity Assessed (UKCA). | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1k | There is a procedure for handling returned products. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1l | There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and /or cells are transferred to another licensed establishment or establishments. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1m | The criteria for allocating tissues and/or cells to patients and health care institutions are documented and made available to these parties on request. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1n | The establishment ensures imports from third countries meet the standards of quality and safety set out in Directions 001/2021. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1o | There is a complaints system in place. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1p | There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and cells. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1q | There is a record of agreements established with third parties. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1r | Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1s | Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ1t | There are procedures for the re-provision of service in an emergency. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ2 | There is a documented system of quality management and audit. | | | |
| GQ2a | There is a quality management system which ensures continuous and systematic improvement. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ2b | There is an internal audit system for all licensable activities. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ2c | An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ2d | Processes affecting the quality and safety of tissues and/or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results. | | | 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. | | | |
| GQ3a | There are clearly documented job descriptions for all staff. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ3b | There are orientation and induction programmes for new staff. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ3c | There are continuous professional development (CPD) plans for staff and attendance at training is recorded. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ3d | There is annual documented mandatory training (e.g. health and safety and fire). | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ3e | Personnel are trained in all tasks relevant to their work and their competence is recorded. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ3f | There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ3g | There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ3h | There is a system of staff appraisal. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ3i | Where appropriate, staff are registered with a professional or statutory body. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ3j | | There are training and reference manuals available. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ3k | | The establishment is sufficiently staffed to carry out its activities. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ4 | | There is a systematic and planned approach to the management of records. | | |
| GQ4a | | There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ4b | | There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ4c | | Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ4d | | There is a system for back-up/recovery in the event of loss of computerised records. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ4e | | The establishment keeps a register of the types and quantities of tissues and/or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ4f | | There are procedures to ensure that donor documentation, as specified by Directions 001/2021, is collected and maintained. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ4g | | There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2021. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ4h | | Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and/or cells. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ4i | | The minimum data to ensure traceability from donor to recipient as required by Directions 001/2021 are kept for 30 years after the use, expiry or disposal of tissues and /or cells. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ4j | | Records are kept of products and material coming into contact with the tissues and/or cells. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ4k | | There are documented agreements with end users to ensure they record and store the data required by Directions 001/2021. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ4l | | The establishment records the acceptance or rejection of tissue and/or cells that it receives and in the case of rejection why this rejection occurred. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ4m | | In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ5 | | There are documented procedures for donor selection and exclusion, including donor criteria. | | |
| GQ5a | | Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 001/2021. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ5b | | The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 001/2021. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ5c | | In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ5d | | There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ5e | | Testing of donor samples is carried out using UKCA or CE marked diagnostic tests, in line with the requirements set out in Directions 001/2021. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ5f | | Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ6 | | A coding and records system facilitates traceability of tissues and cells, ensuring a robust audit trail. | | |
| GQ6a | | There is a donor 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: | | | | |
| GQ6b | | An audit trail is maintained, which includes details of when the tissues and/or cells were acquired and from where, the uses to which the tissues and/or cells were put, when the tissues and/or cells were transferred elsewhere and to whom. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ6c | | The establishment has procedures to ensure that tissues and /or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ6d | | The requirements of the Single European Code are adhered to as set out in Directions 001/2021 **(Northern Ireland only).** | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ7 | | There are systems to ensure that all adverse events, reactions and/or incidents are investigated properly. | | |
| GQ7a | | There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ7b | | There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ7c | | The responsibilities of personnel investigating adverse events and reactions are clearly defined. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ7d | | There are procedures to identify and decide the fate of tissues and/or cells affected by an adverse event, reaction or deviation from the required quality and safety standards. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ7e | | In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ7f | There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ7g | Establishments distributing tissue and/or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ7h | Establishments distributing tissues or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ8 | Risk assessments of the establishment’s practices and processes are completed regularly and are recorded and monitored appropriately. | | | |
| GQ8a | There are documented risk assessments for all practices and processes. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ8b | Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells. | | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ8c | | Staff can access risk assessments and are made aware of local hazards at training. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| GQ8d | | A documented risk assessment is carried out to decide the fate of any tissue and/or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and/or cells. | | Not applicable  Not met  Met |
| Please provide examples: | | | | |
| Premises, Facilities and Equipment | | | | |
| PFE1 | | The Premises are fit for purpose. | | |
| PFE1a | | A risk assessment has been carried out of the premises to ensure that they are fit for purpose. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE1b | | There are procedures to review and maintain the safety of staff, visitors and patients. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE1c | | The premises have sufficient space for procedures to be carried out safely and efficiently. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE1d | | Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE1e | | There are procedures to ensure that the premises are secure and confidentiality is maintained. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE1f | | There is access to a nominated, registered medical practitioner and/or a scientific advisor to provide advice and oversee the establishment’s medical and scientific activities. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE2 | | Environmental controls are in place to avoid potential contamination. | | |
| PFE2a | | Tissues and/or cells stored in quarantine are stored separately from tissue and/or cells that have been released from quarantine. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE2b | | Where processing of tissues and/or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 001/2021. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE2c | | There are procedures for cleaning and decontamination. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE2d | | Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and /or cells and the risk of infection to themselves. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE3 | | There are appropriate facilities for the storage of tissues and cells, consumables and records. | | |
| PFE3a | | Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE3b | | There are systems to deal with emergencies on a 24 hour basis. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE3c | | Tissues and/or cells are stored in controlled, monitored and recorded conditions that maintain tissue and/or cell integrity. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE3d | | There is a documented, specified maximum storage period for tissues and/or cells. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE4 | | Systems are in place to protect the quality and integrity of tissues and/or cells during transport and delivery to a destination. | | |
| PFE4a | | There is a system to ensure tissue and/or cells are not distributed until they meet the standards laid down by Directions 001/2021. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE4b | | There are procedures for the transport of tissues and/or cells which reflect identified risks associated with transport. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE4c | | There is a system to ensure that traceability of tissues and/or cells is maintained during transport. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE4d | | Records are kept of transportation and delivery. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE4e | | Tissues and/or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE4f | | There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE4g | | Critical transport conditions required to maintain the properties of tissues and/or cell are defined and documented. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE4h | | Packaging and containers used for transportation are validated to ensure they are fit for purpose. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE4i | | Primary packaging containing tissue and/or cells is labelled with the information required by Directions 001/2021. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE4j | | Shipping packaging containing tissue and/or cells is labelled with the information required by Directions 001/2021. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE5 | | Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored. | | |
| PFE5a | | Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE5b | | Critical equipment is maintained and serviced in accordance with the manufacturer’s instructions. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE5c | | Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE5d | | New and repaired equipment is validated before use and this is documented. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE5e | | There are documented agreements with maintenance companies. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE5f | | Cleaning, disinfection and sanitation of critical equipment is performed regularly, and this is recorded. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE5g | | Instruments and devices used for procurement are sterile, validated and regularly maintained. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE5h | | Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE5i | | Staff are aware of how to report an equipment problem. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE5j | | For each critical process, the materials, equipment and personnel are identified and documented. | Not applicable  Not met  Met | |
| Please provide examples: | | | | |
| PFE5k | | There are contingency plans for equipment failure. | Not applicable  Not met  Met | |
| Please provide examples: | | |  | |

|  |  |  |
| --- | --- | --- |
| Disposal | | |
| D1 | There is a clear and sensitive policy for disposing of tissues and cells. | |
| D1a | The disposal policy complies with HTA’s Codes of Practice. | Not applicable  Not met  Met |
| Please provide examples: | | |
| D1b | The disposal procedure complies with Health and Safety recommendations. | Not applicable  Not met  Met |
| Please provide examples: | | |
| D1c | There is a documented procedure on disposal which ensures that there is no cross contamination. | Not applicable  Not met  Met |
| Please provide examples: | | |
| D2 | The reasons for disposal and the methods used are carefully documented. | |
| D2a | There is a procedure for tracking the disposal of tissue and/or cells that details the method and reason for disposal. | Not applicable  Not met  Met |
| Please provide examples: | | |
| D2b | Disposal arrangements reflect (where applicable) the consent given for disposal. | 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 the relevant documents** from the list below. If you are unable to provide any of the documents, please explain why below.

|  |  |
| --- | --- |
| Application Checklist – Mandatory documents | |
| Consent | |
|  | Consent form |
|  | Patient information sheet (or equivalent) |
| Governance and Quality Systems | |
|  | Organisational chart |
|  | Quality manual |
|  | List of SOPs of licensable activities |
|  | Details of induction programme for new staff/training plan |
|  | List of providers where TPAs, SLAs or other agreements are/will be in place (e.g. testing labs, courier services) |
|  | Policy for record creation, access, amendment, retention and destruction |
|  | Traceability SOP |
|  | Adverse events/reactions policy |
|  | List of risk assessments relevant to licensable activities |
|  | (Procurement only) Donor selection SOP |
|  | (Testing only) Description of flow for testing samples, from sample procurement until analysis |
|  | (Processing only) PPD(s) for each processing process (See [Preparation Process Dossiers guidance](https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/preparation-process-dossiers-guidance) for further information) |
|  | Transport validation information, for any transportation steps undertaken by your establishment. |

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| Premises, Facilities and Equipment | | |
|  | Risk assessment of premises | |
|  | List of critical facilities, equipment, materials and reagents | |
| Disposal | | |
|  | Disposal policy | |
| Import | | \* Not required for one-off imports |
|  | Completed import spreadsheet. | |
|  | A detailed description of the flow of imported tissues and cells from their procurement to their reception at the importing tissue establishment. | |
|  | A copy of the written agreement with the third country supplier(s). \* | |
|  | A copy of the third country supplier's export authorisation certificate or, where a specific export authorisation certificate is not issued, certification from the relevant third country competent authority or authorities authorising the third country supplier's activities in the tissue and cells sector including exports. This documentation shall also include the contact details of the third country competent authority or authorities. In third countries where such documentation is not available, alternative forms of documentation shall be provided such as reports of audits of the third country supplier. \* | |
|  | A detailed description of the criteria used for donor identification and evaluation. \* | |
|  | Detailed information on the testing centre(s) used by third country suppliers and the tests performed by such centres. \* | |
|  | Where tissues and cells for human application are processed before receipt by the ITE without a subsequent validated microbial inactivation or terminal sterilisation process: information about the environmental monitoring that is performed during critical processing. | |
|  | Detailed information on the conditions for release of tissues and cells by the third country supplier or suppliers. \* | |
|  | A copy of the primary label, repackage label, external package and transport container labels. \* | |
|  | A list of relevant SOPs relating to your proposed import activities including SOPs on applying the Single European Code **(Northern Ireland only)**, reception and storage of imported tissues and cells at the importing tissue establishment, management of serious adverse events and reactions, management of recalls and traceability from donor to recipient. | |
|  | **For one-off imports only:**   * Policy for importing on a one-off basis * SOPs describing:   + how to select a supplier   + how to verify export authorisation certificate requirements   + how to ensure that the imported material has equivalent standards of quality and safety to those set out in HTA Directions 001/2021. The HTA’s tools for assessing equivalence on our website may be helpful:     - [Establishments in Great Britain](https://content.hta.gov.uk/sites/default/files/2021-06/GB%20Tool%20for%20assessing%20equivalent%20quality%20and%20safety%20of%20imported%20tissues.docx)     - [Establishments in Northern Ireland](https://content.hta.gov.uk/sites/default/files/2021-06/Northern%20Ireland%20Tool%20for%20assessing%20equivalent%20quality%20and%20safety%20of%20imported%20tissues.docx)   + how application to the intended recipient will be ensured * Copies of any agreements / contracts that will form part of the one-off import process | | |

Further information on documentation

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Please return this application form by email to [licensing.enquiries@hta.gov.uk](mailto:licensing.enquiries@hta.gov.uk)