Licence application form for establishments in Northern Ireland importing tissues and cells for Human Application from suppliers licensed by the HTA in Great Britain

This licence application form is intended for use by establishments based in Northern Ireland (NI) receiving tissues and cells for human application from HTA-licensed establishments in Great Britain (GB).

As set out in published GOV.UK [guidance on the quality and safety of human organs, tissues and cells](https://www.gov.uk/guidance/quality-and-safety-of-human-organs-tissues-and-cells), if you receive tissues or cells from Great Britain, you will need:

* an import licence; and
* an import agreement with the supplier in Great Britain.

If you undertake, or intend to undertake, any other activities with tissues or cells for human application (such as the storage of cellular products for more than 48 hours, onward distribution, export, procurement, testing or processing), please get in touch as soon as possible via [licensing@hta.gov.uk](mailto:licensing@hta.gov.uk) to discuss your requirements.

# 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;
* [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); and,
* the [HTA’s latest UK Transition guidance](https://www.hta.gov.uk/guidance-professionals/uk-transition-guidance).

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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. the main site with remote satellite sites), a separate satellite licence will be needed for each additional site. | |
| **Premises name** |  |
| **Address** |  |
| **Type of organisation (e.g. Dental Practice, Hospital)** |  |
| **Activity to be licensed at the main site** | **Import of tissue and cell products from GB only.**  If you intend to import cellular tissue and cells for human application and store them for more than 48 hours, please contact us as soon as possible via [licensing@hta.gov.uk](mailto:licensing@hta.gov.uk) to discuss your application. |

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| Part 2: [Satellite sites](http://www.hta.gov.uk/licensingandinspections/satellitepremises.cfm) | | |
| Will the establishment have any satellite sites that will be importing tissues or cells for human application? | | Yes  No |
| If yes, please provide the information below for each satellite site. If you have more than one satellite, please copy and paste this part of the form onto a separate sheet. | | |
| **Premises name** |  | |
| **Address** |  | |
| **Activity to be licensed at the satellite site** | **Import of tissue and cell products from GB only.**  If you intend to import cellular tissue and cells for human application and store them for more than 48 hours, please contact us as soon as possible via [licensing@hta.gov.uk](mailto:licensing@hta.gov.uk) to discuss your application. | |

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| Part 3: Supplier information | |
| **Please complete and return the following spreadsheet with your application:** | |
| **Earliest anticipated date of next import of tissue and cell products from your GB supplier(s)** | DD/MM/YYYY |

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| Part 4: 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 information for DIs we have published on our website: [Useful information for DIs and Named Contacts](https://www.hta.gov.uk/guidance-professionals/licensing/designated-individuals-and-licence-holders-under-human-tissue) | | | | | |
| **Title** | |  | | | |
| **Forename(s)** | |  | | | |
| **Surname** | |  | | | |
| **If you have been known by another name, please provide details** | |  | | | |
| **Correspondence address** | |  | | | |
| **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 practical experience in the fields of medicine, biological science, managerial experience and training** | |  | | | |
| 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, 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 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. | | | | | 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. | | | | | 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. | | | | | 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 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 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 | |
| Part 5: Application to be Individual [Licence Holder](http://www.hta.gov.uk/licensingandinspections/peopleatlicensedestablishments/disandlicenceholdersundertheq&sregulations.cfm) (LH) | | | | | |
| This section should be completed if 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  If the proposed DI is to be the LH, please complete the declaration section only | | | | | |
| **Title** |  | | | | |
| **Forename(s)** |  | | | | |
| **Surname** |  | | | | |
| **If you have been known by another name, please provide details** |  | | | | |
| **Email** |  | | | | |
| **Telephone** |  | | | | |
| **Correspondence address if different from licensed premises** |  | | | | |
| **Job title** |  | | | | |
| **Employing body or organisation** |  | | | | |
| **Membership of relevant professional bodies and registration numbers where applicable** |  | | | | |
| **Details of any other relevant experience, including managerial experience and training** |  | | | | |
| 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 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 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 the licensed activity. | | | Yes  No | | |
| Name: | | | Date: DD/MM/YYYY | | |

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| Part 6: Application to be Corporate [Licence Holder](http://www.hta.gov.uk/licensingandinspections/peopleatlicensedestablishments/disandlicenceholdersundertheq&sregulations.cfm) (LH) | | |
| This section should 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** |  | |
| 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 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 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. | | Yes  No |
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| Name: | | Date: DD/MM/YYYY |

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| Part 7: Supplementary Information | | |
| This section aims to gather further information about the receipt and use of tissue and cell products at your organisation. | | |
| **With regard to the receipt and use of human tissues and cells at your organisation, please indicate whether** | You have procedures in place for the receipt of these materials which include checks by trained staff to confirm that the quality and safety of the product are suitable. For example, that the correct material was received and the packaging is complete and undamaged. | Yes  No |
| You have procedures in place to ensure that these materials are stored in a clean, secure environment and in accordance with any guidance provided in the product packaging and by the supplying organisation. | Yes  No |
| You have an end user agreement in place with your supplier in GB. | Yes  No |
| You have systems in place to report any serious adverse events and reactions to the GB supplier. | Yes  No |
| You have systems in place to ensure tissues and cells are individually traceable from receipt to use in patient treatment (or disposal / return to the supplier). | Yes  No |
| The responses to the above questions also apply to any satellite sites (refer to Part 2 of this form). | Yes  No |

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