Licence variation form for establishments in the Human Application sector that wish to export human tissues and cells for human application to third countries

# Who should use this form?

This licence application form is intended to be used by establishments who are licensed by the HTA in the Human Application sector and wish to:

* add the activity of ‘Export’ to their existing authorisations; or,
* vary an existing export licence authorisation to add a new tissue type.

# A third country is defined as follows:

1. in relation to the import or export of tissues or cells into, or the export of tissues and cells from, Great Britain (GB), a country other than the United Kingdom (UK);
2. in relation to the import of tissues or cells into Northern Ireland, a country other than Northern Ireland or a European Economic Area (EEA) State; and
3. in relation to the export of tissues or cells from Northern Ireland (NI), a country other than the UK or an EEA State.

This form is to vary an existing licence to add or vary the licensable activity of Export. 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, import, procurement, testing or processing), and do not currently hold a licence for these activities, please get in touch as soon as possible via [licensing.enquiries@hta.gov.uk](mailto:licensing.enquiries@hta.gov.uk) to discuss your requirements.

# Licensing requirement

Exporters must demonstrate that exported tissue or cells intended for human application meet the quality and safety standards as set out in the Human Tissue (Quality and Safety for Human Application) Regulations, 2007 (as amended).

This includes establishments who intend to export tissues and cells as the starting material for the manufacture of an Advanced Therapy Medicinal Product (ATMP).

Export licences are not destination specific. Therefore, if you hold an export licence for the tissue type(s) in question because you already export them to third countries, you do not need to update this authorisation to add new recipient third countries.

# 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).

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

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| Part 1: Exporting Tissue 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. | |
| **Establishment name** |  |
| **Establishment licence number** |  |
| **Address of licensed premises** |  |
| **Activity to be licensed at the hub site** | **export of tissue and cell products for human application only.**  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, import, procurement, testing or processing), and do not currently hold a licence for these activities, please get in touch as soon as possible via [licensing.enquiries@hta.gov.uk](mailto:licensing.enquiries@hta.gov.uk) to discuss your requirements. |
| **Brief synopsis of proposed export activity, and tissue/cell pathway prior to export.** |  |
| **Who takes responsibility for any courier steps during export?** | Please specify: |

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| Part 2: [Site](http://www.hta.gov.uk/licensingandinspections/satellitepremises.cfm)(s) undertaking export | |
| Will the establishment have other sites where export will be undertaken, in addition or instead of the hub site listed in Part 1? | Yes  No  If the export will be undertaken by a third party acting under agreement with your establishment, please complete Part 3. |
| If yes, please provide the information below for each site, including satellite sites. If there will be more than one additional site of reception, please copy and paste this part of the form onto a separate sheet: | |
| **Premises name** |  |
| **Address** |  |
| **Activity to be licensed at the satellite site** | **export of tissue and cell products for human application only.**  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, import, procurement, testing or processing), and do not currently hold a licence for these activities, please get in touch as soon as possible via [licensing.enquiries@hta.gov.uk](mailto:licensing.enquiries@hta.gov.uk) to discuss your requirements. |

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| Part 3: Third parties |
| **If export will be undertaken by a third party on behalf of the licensed establishment, please complete this spreadsheet and submit it with your application.** |
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| Part 4: Self-assessment against the requirements for export. |

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| Please complete the following self-assessment. | |
| **Do you have:** | **Self-assessment:** |
| **A written agreement with the recipient organisation in the third country setting out responsibilities for all parties throughout the tissue or cell pathway, including:**   * **transportation,** * **traceability; and,** * **Serious Adverse Events and Reactions (SAEARs) reporting.** | Yes  No  Please include a copy of the agreement with your application or [contact the HTA](mailto:licensing.enquiries@hta.gov.uk) to discuss. |
| **A written agreement with any third parties undertaking activities related to export on behalf of your establishment.** | Yes  No  Please include a copy of the agreement with your application or [contact the HTA](mailto:licensing.enquiries@hta.gov.uk) to discuss. |
| **A documented release process that includes confirmation by a suitably trained and experienced person that the material meets the requirements of the Human Tissue (Quality and Safety for Human Application) Regulations, 2007 (as amended).** | Yes  No |
| **Where your establishment takes responsibility for transportation during export, documented validation of the transportation container demonstrating specified time and temperature requirements during transport will be maintained** | Not applicable  Yes  No  If ‘yes’ please supply a copy of the validation report. If ‘no’ please clarify the information available regarding the suitability of the transportation container: |

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| Part 6: Supporting documents | |
| The following documents all need to be included in support of your application. If any documents are not available, please indicate and provide a comment in the box provided. | |
|  | A completed third party spreadsheet (see part 3), where applicable. |
|  | A copy of the written agreement with any third parties undertaking activities related to export on behalf of your establishment. |
|  | A copy of the written agreement with the recipient organisation in the third country setting out responsibilities for all parties throughout the tissue or cell pathway. |
|  | A copy of your establishment’s documented release procedure. |
|  | Where your establishment takes responsibility for transportation following export, a copy of the validation data/report demonstrating that the required time and temperature requirements during transport will be maintained. |

**Comment of any mandatory documents which have not yet been included with this application and the reason for this:**

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**State the total number of documents included with your application:**

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| Part 8: Designated Individual (DI) Declaration | |
| The DI for the licence must complete this section | |
| **DI Name** |  |
| **DI job role** |  |
| **Telephone number** |  |
| **Email address** |  |
| **Declaration** | I, (*name of DI*), have assured myself of the suitability of the practices set out in this application and authorise the contact person named above to provide this information on my behalf.  I am aware that under paragraph 7(2)(a) of Schedule 3 of the Human Tissue Act 2004, the Human Tissue Authority may revoke a licence if it is satisfied that any information given for the purposes of the application for a licence was in any material respect false and misleading. |
| Signature: |
| Date: DD/MM/YYYY |

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| Part 7: Contact details for the application | |
| Please provide the details of the contact person for this application, **if this is not the DI**. | |
| **Name of contact person for the application** |  |
| **Job role of contact person** |  |
| **Telephone number** |  |
| **Email address** |  |

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