Application for a New/Importing Tissue Establishment Authorisation

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| **For establishments only applying for an importing tissue establishment authorisation, i.e. only performing an importing activity, complete only sections 1, 6, 10 - 15.** **If performing additional tissue establishment activities, complete all relevant sections of the application form.**‘Tissue establishment’ means a tissue bank or a unit of a hospital or another body where activities of donation, procurement, testing, processing, preservation, storage or distribution of human tissues and cells are undertaken.‘Importing tissue establishment’ means a tissue bank or a unit of a hospital or another body established within the European Union which is a party to a contractual agreement with a third country supplier for the import into the European Union of tissues and cells coming from a third country intended for human application.‘Importing activity’ means any activity consisting of any aspect of - (a) the importation of human tissues and cells intended for human application into the European Union; (b) the importation of manufactured products derived from human tissues and cells intended for human application, where those products are not covered by other European Union legislation; (c) the importation of human tissues and cells which are intended to be used exclusively in manufactured products which are covered by other European Union legislation. |

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| 1. Application Details
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| * 1. NEW/IMPORTING TISSUE ESTABLISHMENT DETAILS

**For internal use only:**Draft authorisation no:Licensing register ref no: Fee codes:CWS reference no:Name of new/importing tissue establishment:      Legally registered address of new/importing tissue establishment:      Eircode:      Companies Registration Office number:      Site address of new/importing tissue establishment:      Eircode:       |
| * 1. RESPONSIBLE PERSON

‘Responsible Person’ (RP) in relation to a new/importing tissue establishment means the person who has been designated pursuant to Regulation 8 of the European Communities (Quality and Safety of Human Tissues and Cells) Regulations (S.I. 158 of 2006) as the responsible person for that new/importing tissue establishment.Please provide the name and contact details for the Responsible Person:

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| Name of RP |       |
| Contact address |       |
| Eircode |       |
| Email |       |
| Telephone |       |
| Fax |       |
| RP 24-hour contact details |       |
| Qualifications |       |

Please provide the name and contact details for the delegate RP(s):

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| Name of delegate RP |       |
| Contact address |       |
| Eircode |       |
| Email |       |
| Telephone |       |
| Fax |       |
| RP 24-hour contact details |       |
| Qualifications |       |

Please specify the functions that have been delegated to the above person(s):      Attach the curriculum vitae (CVs) of the above named RP and delegate RP(s). |
| * 1. OTHER LICENCES/AUTHORISATIONS HELD

(This is relevant only to other licences/authorisations granted by the Health Products Regulatory Authority.)Name and address of licensed/authorised establishment:      Licence/authorisation number:       |

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| 1. Prescribed activities
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| ‘Prescribed activity’ means any activity consisting of any aspect of:* the donation, procurement, testing, processing, preservation, storage and distribution of tissues or cells for human applications;
* the donation, procurement, testing, processing, preservation, storage and distribution of tissues or cells for use in manufactured products, where these products are not covered by other Directives;
* the donation, procurement and testing of tissues and cells for use in manufactured products, where these products are covered by other Directives.

‘Site’ means any premises at which any prescribed activities are carried out.In the table below, please:* provide a list of the prescribed activities under the control of the applicant tissue establishment;
* include the name/type of the tissue/cell for which each activity applies;
* provide the name and addresses (including Eircodes) of the specific sites at which each activity will be carried out.

The following is an example:*Prescribed activity: Storage**Tissue/cell: Tendons**Name and address of site where prescribed activity occurs: A.N. Other Laboratory, A.N. Other Hospital, A.N. Other Town, A.N. Other County, etc.*

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| **Prescribed activity** | **Tissue/cell** | **Name and address of site where prescribed activity occurs** |
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Please include any additional relevant information relating to the above activities as required:       |

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| 1. PrOCurement of Human Tissues and Cells
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| ‘Procurement’ means any process by which tissues and cells are made available.‘Procurement organisation’ means a healthcare establishment or a unit of a hospital or another body that undertakes the procurement of human tissues and cells.In the table below, please:* provide the name(s) and address(es) (including Eircodes) of the site(s) where procurement of the tissues/cells specified in section 2 will take place;
* indicate the tissue/cell that will be procured at each site.

The following is an example:*Procurement organisation/site: Operating Theatre, A.N. Other Hospital, A.N. Other Town, A.N. Other County, etc.**Tissue/cell procured: Haematopoietic stem cells – bone marrow*

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| **Procurement organisation/site** | **Tissue/cell procured** |
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Please include any additional relevant information relating to the above activities as required:       |

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| 1. tissue and cell preparation process
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| ‘Processing’ means all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications.For the purposes of this application the following processes as they apply should be listed:cutting, grinding, shaping, centrifugation, soaking in antibiotic or antimicrobial solutions, sterilisation, irradiation, cell separation, cell concentration, cell purification, filtering, lyophilisation, freezing, cryopreservation, vitrification.The following processes should be listed as they apply to assisted reproduction:*in-vitro* fertilisation (IVF), intracytoplasmic sperm injection (ICSI), intrauterine insemination (IUI), cryopreservation, vitrification, thawing, assisted hatching (chemical and mechanical), embryo biopsy.**Other ‘processes’ may also be listed and will be discussed with each tissue establishment prior to inclusion on a tissue establishment authorisation.**In the table below, please:* list and provide details of each tissue/cell preparation process(es) that will be carried out at the applicant tissue establishment;
* include the name/type of the tissue/cell for which each process applies.

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| **Process(es) performed by the tissue establishment** | **Tissue/cell(s) to which process is applied** |
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Please include any additional relevant information relating to the above activities as required:      |

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| 1. Tests required for donors
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| Donors of tissues and cells, except donors of reproductive cells, must undergo the biological tests set out in point 1 of Schedule 2 of the European Communities (Quality and Safety of Human Tissues and Cells) Regulations (S.I. 158 of 2006), as amended.Donors of reproductive cells must undergo the biological tests set out in points 1, 2 and 3 of Schedule 3 of the European Communities (Quality and Safety of Human Tissues and Cells) Regulations (S.I. 158 of 2006), as amended.Note: The laboratories that carry out the tests specified above must be authorised by the HPRA by being listed on the tissue establishment authorisation of the applicant tissue establishment in accordance with the requirements of the European Communities (Quality and Safety of Human Tissues and Cells) Regulations (S.I. 158 of 2006).With this application, you must provide copies of contract/service level agreements in place with each testing laboratory.In the table below, please provide:* the name and addresses (including Eircodes) of the laboratories that will carry out the tests specified above;
* the tests that will be performed by each laboratory on behalf of the tissue establishment.

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| **Name of laboratory** | **Address of laboratory** | **Tests performed by laboratory** |
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Please include any additional relevant information relating to the above activities as required:      |

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| 1. Importing Tissue Establishments
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| Please note that the import of human tissues and cells applies only to such import from ‘third countries’, i.e. outside the European Union. Please complete the details requested below:**Details of tissues and cells to be imported:**

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| Types of tissues and cells to be imported, including one-off imports of specific types of tissues and cells | Product name (and where applicable, in accordance with the EU generic list) of all tissues and cells to be imported | Trade name (if different from the product name), of all tissues and cells to be imported  | Name of third country supplier for each type of tissue and cell to be imported |
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**Location of tissue and cell activities:*****Note: activities include – donation, procurement, testing, processing, preservation, and storage***

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| Tissue or cell | List activities which are carried out prior to import by the third country supplier per type of tissue and cell | List activities which are carried out prior to import by sub-contractors of the third country supplier per tissue and cell type | List activities carried out by the importing tissue establishment subsequent to import per tissue and cell | List the third countries in which activities prior to import take place per type of tissue and cell |
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**Details of third country supplier:**

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| Name of third country supplier(s) (company name) |       |
| Name of contact person |       |
| Site address |       |
| Postal address (if different) |       |
| Telephone number (incl. international dialling code) |       |
| Emergency contact number (if different) |       |
| Email address |       |

The following documents must also accompany the application:1. A copy of the written agreement with the third country supplier(s). 2. A detailed description of the flow of imported tissues and cells from their procurement to their reception at the importing tissue establishment. 3. 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.4. Documentation relating to the importing tissue establishment:1. A job description of the Responsible Person and details of his/her relevant qualifications and training record as laid down in Directive 2004/23/EC;
2. A copy of the primary label, repackage label, external package and transport container;
3. A list of relevant and up-to-date versions of standard operating procedures (SOPs) relating to the establishment's import activities including SOPs on applying the Single European Code, reception and storage of imported tissues and cells at the importing tissue establishment, management of adverse events and reactions, management of recalls and traceability from donor to recipient.

5. Documentation relating to the third country supplier or suppliers: 1. A detailed description of the criteria used for donor identification and evaluation, information provided to the donor or donor family, how consent is obtained from the donor or donor family and whether the donation was voluntary and unpaid or not;
2. Detailed information on the testing centre(s) used by third country suppliers and the tests performed by such centres;
3. Detailed information on the methods used during the processing of the tissues and cells including details of the validation for the critical processing procedure;
4. A detailed description of the facilities, critical equipment and materials and criteria used for quality control and control of the environment for each activity carried out by the third country supplier;
5. Detailed information on the conditions for release of tissues and cells by the third country supplier or suppliers;
6. Details of any sub-contractors used by the third country suppliers including the name, location and activity undertaken;
7. A summary of the most recent inspection of the third country supplier by the third country competent authority or authorities including the date of the inspection, type of inspection and main conclusions;
8. A summary of the most recent audit of the third country supplier carried out by, or on behalf of, the importing tissue establishment;
9. Any relevant national or international accreditation.
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| 1. EXPORT OF HUMAN TISSUES AND CELLS
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| Please note that the export of human tissues and cells applies only to such export to ‘third countries’, i.e. outside the European Union. In the table below, please:* provide the name(s) and address(es) of the tissue establishments/organisations responsible for human application to which human tissues/cells to be exported;
* include the name/type of the tissues/cells to be exported to the named sites;
* indicate if the export is to occur on a routine/for immediate transplant/emergency only basis.

**Please provide copies of the service level agreement in place with each tissue establishment/organisation responsible for human application.**

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| **Name and address of site** | **Tissue/cell exported** | **Export to be performed on a routine/for immediate transplant/emergency only basis** |
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| 1. relations between tissue establishments and third parties
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| Tissue establishments must establish written agreements with a third party each time an external activity takes place which influences the quality and safety of tissues and cells processed in cooperation with a third party in accordance European Communities (Quality and Safety of Human Tissues and Cells) Regulations (S.I. 158 of 2006), as amended. Please review the above legislation prior to completing this section. In the table below, please:* provide the name(s) and address(es) (include postcodes) of the third party(ies) that will undertake such an activity(ies).
* specify the activity/process, which will be undertaken by the above named third party(ies).
* specify the human tissue/cell to which each activity relates.

The following are examples:*Name and address of third party: A.N. Other Hospital, A.N. Other Address.**Prescribed activity/process: Procurement**Tissue/cell to which prescribed activity/process applies: Cadaveric bone**Name and address of third party: A.N Other Distributor, A.N. Other Address.**Prescribed activity/process: Distribution**Tissue/cell to which prescribed activity/process applies: Sperm***Please provide copies of the service level agreement in place with each third party.**

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| **Name and address of third party** | **Prescribed activity/process** | **Tissue/cell to which prescribed activity/process applies** |
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Please include any additional relevant information relating to the above activities as required:       |

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| 1. List of organisations responsible for human application supplied by the applicant tissue establishment
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| ‘Organisations responsible for human application’ means a healthcare establishment or a unit of a hospital or another body which carries out human application of human tissues and cells. In the table below, please provide a list of ‘organisations responsible for human application’ which will be supplied by the tissue establishment.Please provide copies of the agreement in place with each organisation responsible for human application.

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| **Name of organisation** | **Address of organisation** |
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| 1. quality system
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| The tissue establishment/importing tissue establishment is required to have a quality system in place prior to inspection. A quality system requires the tissue establishment/importing tissue establishment to have a documented set of procedures which contain and describe, in sufficient detail, all the activities which could affect the quality of the tissues/cells. The applicant must submit a list of the procedures in its quality system. Reference: S.I. 598 of 2007, as amended.  |
| 1. RECORDS
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| Please provide an overview of the systems in place to ensure the appropriate retention of traceability records for defined periods, as required by national and EU legislation. |
| 1. Contingency Plan
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| Please provide a copy of the service level agreement in place with another tissue establishment for the storage of tissues and cells and relevant files in the event of termination of activities. |
| 1. fees
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| An application fee must be submitted with each request for an authorisation. Please refer to the **HPRA Guide to Fees for Human Products** onthe ‘Publications and Forms’ section of [www.hpra.ie](http://www.hpra.ie)and complete the fee application form.[ ]  Tick to confirm that the fee application form has been completed and submitted with this application.[ ]  Tick to confirm that the appropriate fee has been attached. |
| 1. declaration
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| In the event of the authorisation being granted, I undertake to ensure fulfilment of the obligations arising by virtue of the terms and conditions of the authorisation and declare that the above particulars are, to the best of my knowledge and belief, correct.**Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**       (Responsible Person)**Print name**:       **Title/position:**      **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**       (CEO/Medical Director)**Print name**:       **Title/position:**       |
| 1. checklist of documents
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| The following information must be submitted with the application (except where not applicable).Please tick the boxes below to confirm the documents have been included with the application.[ ]  Certificate of incorporation (section 1)[ ]  Business document from Companies Registration Office if using a trading style[ ]  Completed application form [ ]  Statement on the suitability of the premises [ ]  Overview of record retention[ ]  Statement on quality system (including a list of procedures)[ ]  CV(s) for Responsible Person(s)[ ]  Documentation required for importing tissue establishment[ ]  Contingency plan and outline for traceability records[ ]  Fee application form (section 13)[ ]  Relevant fee (section 13)[ ]  Signed declaration (section 14)[ ]  Copy of new site plans[ ]  Detailed plan including timeframes for qualification of premises and the purchase and qualification of equipment |
| Note: Please contact the Health Products Distribution section within the Compliance department in the HPRA in relation to any requirements for controlled drugs.  |

Send to:

Compliance Department

Health Products Regulatory Authority

Earlsfort Centre

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Dublin 2

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