Tissue Establishment Annual Report

**Please note this form is NOT to be used for reproductive tissues/cells.**

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| --- | --- |
| Annual report year: |  |

**PART A – DETAILS OF TISSUE ESTABLISHMENT**

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| --- | --- |
| Name of tissue establishment |  |
| Full address of tissue establishment |  |
| Authorisation number | **TE-** |

**PART B**

**Section 1 – Activities undertaken**

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| --- | --- | --- | --- |
| **List of Activities** | **Tick if activity is undertaken by your TE** | **Tick if activity is undertaken by a third party on behalf of your TE** | **Tick if the activity is not applicable** |
| Donation  (Note: this includes autologous donation) |  |  |  |
| Procurement |  |  |  |
| Testing |  |  |  |
| Processing |  |  |  |
| Preservation |  |  |  |
| Storage |  |  |  |
| Distribution/transport |  |  |  |
| Import |  |  |  |
| Export |  |  |  |

**Section 2 – Types of tissues and/or cells**

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| **2.1** Please tick the types of tissues and/or cells that are relevant to your tissue establishment authorisation from the list below. |

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| --- | --- |
| Heart valves |  |
| Other cardiovascular, e.g. pericardium or conduit or patch | <please specify> |
| Vessels |  |
| Bone |  |
| Tendons |  |
| Demineralised bone |  |
| Ligaments |  |
| Other musculoskeletal, e.g. Meniscus | <please specify> |
| Skin |  |
| Cornea |  |
| Sclera |  |
| Other ocular, e.g. limbal stem cells | <please specify> |
| Bone marrow |  |
| Peripheral blood stem cells |  |
| Umbilical cord blood |  |
| Donor lymphocyte infusions |  |
| Other stem cells | <please specify> |
| Amniotic membrane |  |
| Hepatocytes |  |
| Pancreatic islets |  |
| Others, e.g. adipose tissue | <please specify> |

**Section 3 – Quantities of tissues and/or cells**

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| **3.1**  Please complete and copy (if required) the table of questions (table 3.1) for each type of tissue and/or cell relevant to your tissue establishment. |

**Table 3.1**

|  |  |  |  |
| --- | --- | --- | --- |
| Type of tissue or cell | |  | |
| Please select one of the following:  Autologous  Allogeneic related  Allogeneic unrelated | | | |
| 1. | How many units procured? |  | |
| 2. | How many donors (including autologous donors) were tested? |  | |
| 3. | \*How many units processed?  *(NB – See guidance document)* |  | |
| 4. | How many units preserved? |  | |
| 5. | How many units stored? |  | |
| 6. | \*How many units released for treatment?  *(NB – See guidance document)* |  | |
| 7. | \*What is the total number of recipients for this type of tissue/cell?  *(NB – See guidance document)* |  | |
| 8. | How many units accepted into the tissue establishment?  (from other tissue establishments within the EU) |  | Country: |
| 9. | How many units distributed from the tissue establishment?  (to other tissue establishments within the EU) |  | Country: |
| 10. | How many units imported?  (from outside the EU) |  | Country: |
| 11. | How many units exported?  (outside the EU) |  | Country: |
| 12. | How many units otherwise disposed of? |  | |
| 13. | How many units were not fully traceable from donor to recipient? |  | |

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| **Any relevant additional information** |
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**PART C – DECLARATIONs**

**Section 1 – Only to be completed by tissue establishments authorised for import**

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| I declare that the most up-to-date version of the documents detailed in Annex III of Directive 2015/566 are maintained by the tissue establishment and available at the request of the HPRA.  Signature:       Date:  Print name:       Title/position:  (To be signed by the person who has completed the annual report.) |

**Section 2 – To be completed by all tissue establishments**

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| To the best of my knowledge and belief, the information provided in this annual report is correct and complete.  Signature:       Date:  Print name:       Title/position:  (To be signed by the person who has completed the annual report.)  Signature:       Date:  Print name:       Title/position:  (To be signed by the tissue establishment’s Responsible Person.) |

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| Please complete and return annually by **31 March** to:  Compliance Department  Health Products Regulatory Authority  Kevin O’Malley House  Earlsfort Centre  Earlsfort Terrace  Dublin 2  Tel: + 353 1 676 4971  Fax: + 353 1 676 7836  Or email completed scanned copy to: [compliance@hpra.ie](mailto:compliance@hpra.ie). |