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: |

|  |  |
| --- | --- |
| 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**

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| --- | --- | --- |
|  | Type of tissue or cell |       |
|  | Autologous/allogeneic |       |
| 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 EEA)  |       | Country      |
| 9. | How many units distributed from the tissue establishment? (to other tissue establishments within the EEA) |       | Country      |
| 10. | How many units imported?(from outside the EEA)  |       | Country      |
| 11. | How many units exported? (outside the EEA) |       | 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:** |
|       |

**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.) |

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**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 DepartmentHealth Products Regulatory Authority Kevin O’Malley HouseEarlsfort CentreEarlsfort TerraceDublin 2Tel: + 353 1 676 4971Fax: + 353 1 676 7836Or email completed scanned copy to: compliance@hpra.ie. |