**Notification of One-Off (Non-Routine) Import/Export of Tissues and Cells for Human Application**

***Please note:*** *Following the publication of EU Directive 2015/566 a definition has been provided for ‘one-off import’. Previously the HPRA have referred to this activity as ‘non-routine import’. Where ‘non-routine’ was previously referenced in documentation we have now replaced it with ‘one-off’ and included ‘non-routine’ in parentheses.*

Section 1 Activity to be UNDERTAKEN

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| **1.1** One-off (non-routine) import of human tissues/cells |  **[ ]**   |
| **1.2** One-off (non-routine) export of human tissues/cells |  **[ ]**   |

SEction 2 Details of Authorised Irish Tissue Establishment

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| **2.1** Irish tissue establishment name |       |
| **2.2** Authorisation number |       |

Section 3 Details of Organisation outside the EU (i.e. Third Country Organisation)

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| **3.1** Name of third country organisation |       |
| **3.2** Full address of third country organisation |       |
| **3.3** Name of contact person at third country organisation |       |
| **3.4** Email address of contact in third country organisation |       |
| **3.5** Phone number of third country organisation |       |
| **3.6** Emergency contact for third country organisation |       |
| **3.7** Is the third country organisation accredited/authorised/licensed by the relevant authority for tissues/cells in that country? | [ ]  Yes [ ]  No |
| **3.8** Name of the awarding authority |       |
| **3.9** Accreditation/authorisation/licence reference number(s) |       |
| **3.10** Is there a third party agreement in place between the Irish tissue establishment and the third country organisation defining respective responsibilities (to include transport) in relation to the proposed import/export of tissues/cells? | [ ]  Yes [ ]  No |
| **3.11** List the prescribed activities carried out by the third country organisation in relation to ‘one-off (non-routine) import’. | [ ]  Donation[ ]  Procurement[ ]  Testing[ ]  Processing[ ]  Preservation[ ]  Storage |
| **3.12** List the prescribed activities carried out by sub- contractors of the third country organisation in relation to ‘one-off (non-routine) import’. | [ ]  Donation[ ]  Procurement[ ]  Testing[ ]  Processing[ ]  Preservation[ ]  Storage |

Section 4 Details of transport

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| **4.1** Name of organisation to be used for the transport of the tissues/cells |       |
| **4.2** Address of organisation to be used for the transport of the tissues/cells |       |
| **4.3** Phone number of organisation to be used for the transport of the tissues/cells |       |
| **4.4** Name of contact person at organisation to be used for the transport of the tissues/cells |       |
| **4.5** Intended start date of transport of tissues/cells (from/to third country organisation) |       |
| **4.6** Intended date for receipt of tissues/cells at Irish tissue establishment/third country organisation |       |

Section 5 Details of tissues/cells to be imported/exported

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| **5.1** Total number of units of tissues/cells to be imported/exported |       |
| **5.2** Please complete rows below for each unit of tissues and/or cells to be imported/exported. |
| **Type of tissues/cells to be imported/exported** | **Unique code or identification number/SEC as applicable of tissues/cells**  |
|       |       |
|       |       |
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Section 6 Compliance with Tissues and Cells Legislation (FOR IMPORT ONLY)

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| **6.1** Do the tissues/cells to be imported meet the requirements of the tissues and cells legislation (as per Regulation 15[2] of S.I. 158 of 2006, available on the Office of the Attorney General website)? | [ ]  Yes[ ]  No |
| **6.2** If you answered ‘yes’ that the requirements are met, please provide details of how the tissues/cells to be imported meet the requirements of Regulation 15[2] of S.I. 158 of 2006, available on the Office of the Attorney General website. |       |
| **6.3** If you answered ‘no’ that the requirements are not met, please provide details of how the authorised Irish tissue establishment will ensure the requirements of paragraph 2.3 of Schedule 4 of S.I. 158 of 2006 are met, available on the Office of the Attorney General website. |       |

Section 7 Compliance with Tissues and Cells Legislation (FOR exPORT ONLY)

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| **7.1** Do the tissues/cells to be exported meet the requirements of the tissues and cells legislation (as per Regulation 15[3] of S.I. 158 of 2006, available on the Office of the Attorney General website)? | [ ]  Yes[ ]  No |
| **7.2** If no, please provide details of non-compliance. |       |

Section 8 Importing Tissue Establishment

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| **8.1** List the prescribed activities that will be carried out by the importing tissue establishment. |
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Section 9 fees

An application fee must be submitted with each application for one-off import/export of human tissues and cells for human application. Please refer to section 4 of the ‘Guide to Fees for Human Products’ available under the ‘Publications and Forms’ section at [www.hpra.ie](http://www.hpra.ie).

Section 10 Declaration

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| I hereby declare that, to the best of my knowledge and belief, the information given in this notification form is correct and complete. I have also submitted the appropriate fee (code 330) to the HPRA.

|  |  |
| --- | --- |
| Signature:       | Date:        |
|  |  |
| Print name:        | Title/position:        |

(To be signed by the person who has completed the form.)I furthermore declare that if the imported tissues and cells are not subsequently used for the intended recipient, I will inform the HPRA and provide a justification indicating why they were not used for the intended recipient.

|  |  |
| --- | --- |
| Signature:       | Date:        |
|  |  |
| Print name:        | Title/position:        |

(To be signed by the tissue establishment’s Responsible Person.) |

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| Please complete and return to:Compliance Department,Health Products Regulatory Authority Kevin O’Malley HouseEarlsfort CentreEarlsfort TerraceDublin 2D02 XP77Tel: + 353 1 676 4971Fax: + 353 1 676 7836Or email a completed scanned copy to compliance@hpra.ie. |