**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’ on [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 House  Earlsfort Centre  Earlsfort Terrace  Dublin 2  D02 XP77  Tel: + 353 1 676 4971  Fax: + 353 1 676 7836  Or email a completed scanned copy to [compliance@hpra.ie](mailto:compliance@hpra.ie). |