Application for a Variation to a Tissue/Importing Tissue Establishment Authorisation

*Please ensure all relevant sections of this form are completed to validate your variation application.*

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| section 1: Application details | |
| * 1. APPLICANT DETAILS   TE number:  Name of tissue/importing tissue establishment:    Legally registered address of tissue/importing tissue establishment:  Eircode:  Companies Registration Office number:  Address of tissue establishment:  Eircode:  Date of application: | **For internal use only**  Licensing register ref no:  Endorsement no:  Fee codes:  CWS reference no: |
| * 1. RESPONSIBLE PERSON   Name:  Contact address:  Eircode:  Email:  Telephone:  Fax: | |
| * 1. APPLICANT DETAILS *(if different from above)*   Name:  Contact address:  Eircode:  Email:  Telephone:  Fax: | |

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| section 2: Proposed variation to the authorisation | | | |
| **2.1 TYPE OF VARIATION**  Please complete a separate application form for each site. Select the appropriate tick-box to indicate the variation being applied for.  Please note that electronic documentation is preferable. If the supporting documents are too large to be sent by email, the HPRA can provide a link to a secure One Drive Sharepoint. | | | |
| **Type of variation**  **A = Administrative T = Technical** | | **Please tick (√)** | **Supporting documentation required** |
| A | 1. Change in name of the authorisation holder |  | 1. Letter confirming change in name 2. Copy of company registration form or equivalent (if relevant) |
| T | 1. Change in the legally registered address or site address of the tissue establishment/importing tissue establishment |  | If new premises:   1. Letter confirming change of address 2. Copy of company registration form or equivalent 3. Site plan and floor map of new premises 4. Details of suitability of premises and equipment 5. Site Master File or Quality Manual 6. For a change to the legally registered address, please include copy of the Company Registration Office form   If administrative change in address:   1. Letter confirming change of address 2. Copy of company registration form or equivalent (if relevant) |
| A | 1. Change in name of site carrying out a prescribed activity/importing activity *(Schedule 2, Annex 1, Part 1)* |  | Letter confirming change in name |
| T | 1. Change in address of site carrying out a prescribed activity/importing activity *(Schedule 2, Annex 1, Part 1)* |  | If new premises:   1. Letter confirming change of address 2. Site plan and floor map of new premises 3. Details of suitability of premises and equipment 4. Site Master File or Quality Manual   If administrative change in address:  Letter confirming change of address |
| T | 1. Addition of a Responsible Person to the authorisation *(Schedule 2, Annex 3)* |  | 1. Confirmation that new Responsible Person meets the requirements of S.I. 158 of 2006 2. CV of RP to be added to authorisation |
| A | 1. Deletion of a Responsible Person from the authorisation (if there is more than one listed RP on the current authorisation) *(Schedule 2, Annex 3)* |  | Explanation for deletion of Responsible Person from authorisation |
| T | 1. Replacement of a Responsible Person on the authorisation *(Schedule 2, Annex 3)* |  | 1. Explanation for replacement of Responsible Person 2. Confirmation that replacement Responsible Person meets the requirements of S.I. 158 of 2006 3. CV of replacement Responsible Person |
| T | 1. Addition of a Delegate Responsible Person to the authorisation *(Schedule 2, Annex 3)* |  | 1. CV of Delegate Responsible Person to be added to authorisation 2. Details of delegated responsibilities |
| A | 1. Deletion of a Delegate Responsible Person from the authorisation. *(Schedule 2, Annex 3)* |  | Explanation for deletion of Delegate Responsible Person from authorisation |
| T | 1. Replacement of a Delegate Responsible Person on the authorisation *(Schedule 2, Annex 3)* |  | 1. Explanation for replacement of Delegate Responsible Person 2. CV of replacement Delegate Responsible Person |
| A | 1. Addition, deletion or change of address of an organisation(s) responsible for human application supplied by the authorisation holder *(Schedule 2, Annex 4)* |  | 1. Copy of contract or service level agreement between the authorisation holder and the organisation(s) responsible for human application 2. Full name and address of each organisation |
| T | 1. Addition of a new tissue and/or cell to the prescribed activities by the authorisation holder *(Schedule 2, Annex 1, Part 2 or Part 3)* |  | 1. Full details of the type of tissue/cell to be added to authorisation and for which prescribed activities 2. Appropriate validation data 3. Other information as deemed necessary |
| A | 1. Deletion of a named tissue and/or cell by the authorisation holder *(Schedule 2, Annex 1, Part 2 or Part 3)* |  | Explanation for deletion of named tissue/cell from the authorisation and confirmation that tissue/cell will no longer be procured or processed, or otherwise involved in the prescribed activities, by the authorisation holder |
| T | 1. Addition of a site and/or prescribed activity *(Schedule 2, Annex 1, Part 1)* |  | 1. Site Master File/Quality Manual 2. Appropriate validation data |
| A | 1. Deletion of a site and/or prescribed activity *(Schedule 2, Annex 1, Part 1)* |  | Explanation for deletion of site and/or prescribed activity from the authorisation and confirmation that site will not be used and/or prescribed activity will not be carried out. |
| T | 1. Addition of a contractor at which a prescribed activity/process is being carried out *(Schedule 2, Annex 2, Part 1)* |  | 1. Copy of contract/ service level agreement between the authorisation holder and the contractor 2. Copy of process flow documenting the exact prescribed activities/processes performed by the third party contractor 3. Other information as deemed necessary |
| A | 1. Deletion of a contractor at which a prescribed activity/process is being carried out *(Schedule 2, Annex 2, Part 1)* |  | Explanation for deletion of contractor from authorisation and confirmation that contractor will no longer be used by the authorisation holder |
| T | 1. Change in the prescribed activity/process being carried out by a contractor *(Schedule 2, Annex 2, Part 1)* |  | 1. Appropriate validation data 2. Updated contract/service level agreement 3. Other information as deemed necessary |
| T | 1. Changes in relation to the export of tissues and/or cells *(Schedule 2, Annex 2, Part 2)* |  | 1. Details of arrangements in place surrounding the export of tissues/cells 2. Contracts/service level agreements in place with export site 3. Statement by RP that exported tissues/cells meet the requirements of relevant legislation   **Note**: A special condition regarding import/export may be added to the authorisation. |
| T | 1. Changes in relation to importing activities (Appendix 1), i.e. changes in relation to types of tissues or cells imported; changes in relation to third country supplier; change in relation to sub- contractor to third country supplier |  | 1. Type of tissue or cell to be added 2. A detailed description of the flow of imported tissues and cells from their procurement to their reception at the importing tissue establishment 3. Export certificate 4. Written agreement with the third country supplier 5. Details of any sub-contractors used by the third country suppliers including the name, location and activity undertaken 6. The following information must also be provided: 7. 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 8. Detailed information on the testing centre(s) used by third country suppliers and the tests performed by such centres 9. Detailed information on the methods used during the processing of the tissues and cells including details of the validation for the critical processing procedure 10. 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 11. Detailed information on the conditions for release of tissues and cells by the third country supplier or suppliers 12. Details of any sub-contractors used by the third country suppliers including the name, location and activity undertaken 13. 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 14. A summary of the most recent audit of the third country supplier carried out by, or on behalf of, the importing tissue establishment 15. Any relevant national or international accreditation   **Note:** A special condition regarding import/export may be added to the authorisation. |
| T | 1. Changes to the procurement organisation(s) named in the authorisation *(Schedule 2, Annex 1, Part 3)* |  | 1. Appropriate validation data (if relevant) 2. Contract/service level agreement in place with procurement organisation |
| T | 1. Addition of umbilical cord blood/tissue procurers *(Schedule 2, Annex 1, Part 3)* |  | Contract/service level agreement in place with procurement organisation/individuals authorised for procurement named in authorisation |
| A | 1. Deletion of umbilical cord blood/tissue procurers *(Schedule 2, Annex 1, Part 3)* |  | Explanation for deletion of procurer from authorisation and confirmation that procurer will no longer be used by the authorisation holder |
| T | 1. Changes to the testing laboratory(ies) named in the authorisation *(Schedule 2, Annex 1, Part 4)* |  | 1. Contract/service level agreement in place with testing laboratory 2. Confirm the following: 3. A satisfactory audit of the testing laboratory has been performed by the tissue establishment or appropriate designee. 4. Testing laboratory is ISO15189 accredited for the tests they will be performing. 5. Provide details of the testing performed by the laboratory and the laboratory address at which this testing will be performed.   *Please provide justification if confirmation cannot be provided.* |
| T | 1. Changes to the process or processes named in the authorisation *(Schedule 2, Annex 1, Part 2 or part 3)* |  | 1. Reason for change 2. Appropriate validation data 3. Other information as deemed necessary |
| T | 1. Other change/variation. Please specify: |  | * 1. Updated Quality Manual if applicable   2. Appropriate validation data if applicable   3. Other information as deemed necessary |
| T | 1. Changes to the site(s) at which the authorisation holder operates or to the prescribed activities carried out at the named sites which may impact the quality and safety of the tissues and/or cells |  | Appropriate validation data  **Note**: This change may not result in a change to the content of the authorisation but is required to be notified to the HPRA in writing as per Regulation 6 of S.I. 158 of 2006. |
| T | 1. Changes to the quality system that are likely to have a substantial impact on the conduct of, or might compromise the safety of, any of the prescribed activities which the tissue establishment has been authorised to undertake as per the terms of the authorisation |  | 1. Updated Quality Manual or Site Master File 2. Appropriate validation data   **Note**: This change may not result in a change to the content of the authorisation but is required to be notified to the HPRA in writing as per Regulation 6 of S.I. 158 of 2006. |

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| 2.2 PROPOSED WORDING  Please specify the precise present wording in the current tissue/importing tissue establishment authorisation and the proposed wording underlining or highlighting the changed words.  **(Note: Failure to complete this section may result in the application being deemed invalid.)** | |
| **Present wording** | **Proposed wording** |
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| 2.3 BACKGROUND  Please give a brief background explanation for the proposed changes to your authorisation (attach additional supporting data as necessary). | |
| 2.4 FEES  An application fee must be submitted with each request for variation to an authorisation.  Please refer to the ‘Guide to Fees’ on the ‘Publications and Forms’ section of [www.hpra.ie](http://www.hpra.ie) and complete the fee application form. | |

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| section 3: Declaration |
| I hereby make application for the above authorisation to be varied and/or to notify the HPRA in relation to above changes in accordance with the proposals given above and certify that the changes will not adversely affect the quality, efficacy or safety of tissues or cells involved. I declare that amended documents have been supplied and that the supporting information is correct. I declare that all changes have been identified and that there are no other changes in the amended documentation.  I have submitted the appropriate fee as follows:  Per administrative variation - Code 330 Per technical variation - Code 331  **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (Quality Manager)  **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (Responsible Person) |

Send to:

Compliance Department

Health Products Regulatory Authority

Earlsfort Centre

Earlsfort Terrace

Dublin 2

D02 XP77

Tel: + 353 1 676 4971

Fax: + 353 1 676 7836

Email: [compliance@hpra.ie](mailto:compliance@hpra.ie)