Application for a Variation to an Organ Authorisation

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

|  |  |
| --- | --- |
| section 1: Application details | |
| * 1. ORGANISATION DETAILS   Name of organisation:  Address of organisation:  Authorisation number: | **For internal use only**  Licensing register ref no.:  Endorsement no.:  Fee codes:  CWS reference no.: |
| * 1. APPLICANT DETAILS *(if different from above)*   Name:  Contact address:  Email:  Telephone: | |

|  |  |  |  |
| --- | --- | --- | --- |
| 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. Explanation for change in name |
| T | 1. Change in address (site/premises) of the authorisation holder |  | 1. Letter confirming change of address (site/premises) 2. Explanation for change of address (site/premises) 3. Detailed operational plan for change in address (site/premises) to include:  * site plan/description of new premises * details on the suitability of new site/premises and equipment * ‘process flow’ diagram listing all relevant steps of the change in address (site/premises) and the actions taken by the authorisation holder in this regard * updated quality manual * validation master plan * additional supporting document as requested by the HPRA |
| T | 1. Addition of a prescribed activity carried out by authorisation holder   *(Schedule 2 Annex 1 Part 1)* |  | 1. Explanation for addition of prescribed activity 2. Detailed operational plan for addition of prescribed activity, to include:  * ‘process flow’ diagram listing all relevant steps in the addition of prescribed activity and the actions taken by the authorisation holder in this regard * updated quality manual * validation master plan * additional supporting documentation as requested by the HPRA |
| A | 1. Deletion of prescribed activity carried out by the authorisation holder *(Schedule 2 Annex 1 Part 1)* |  | Explanation for deletion of prescribed activity from the authorisation and confirmation that prescribed activity will not be carried out by the authorisation holder |
| T | 1. Addition of an organ to which prescribed activities are carried out by the authorisation holder *(Schedule 2 Annex 1 Part 1)* |  | 1. Explanation for the addition of an organ 2. Detailed operational plan for addition of organ, to include:  * ‘process flow’ diagram listing all relevant steps in the addition of an organ and the actions taken by the authorisation holder in this regard * updated quality manual * validation master plan * additional supporting documentation as requested by the HPRA |
| A | 1. Deletion of an organ to which prescribed activities are carried out by the authorisation holder *(Schedule 2 Annex 1 Part 1)* |  | Explanation for deletion of an organ from the authorisation and confirmation that authorisation holder will not carry out prescribed activities in relation to this organ |
| T | 1. Addition of a site at which a prescribed activity is carried out by the authorisation holder (*Schedule 2 Annex 1 Part 1)* |  | 1. Explanation for the addition of a site at which a prescribed activity is carried out by the authorisation holder 2. Detailed operational plan for the addition of a site, to include:  * site plan/description of premises * details of suitability of site/premises and equipment * ‘process flow’ diagram listing all relevant steps in the addition of the site and the actions taken by the authorisation holder in this regard * updated quality manual * validation master plan * additional supporting documentation as requested by the HPRA |
| A | 1. Deletion of a site at which a prescribed activity is carried out by the authorisation holder (*Schedule 2 Annex 1 Part 1)* |  | Explanation for deletion of site from the authorisation and confirmation that authorisation holder will not carry out prescribed activities at this site |
| T | 1. Change to procurement organisation/site at which procurement activities are carried out by, or in co-operation with, the authorisation holder (*Schedule 2 Annex 1 Part 2)* |  | 1. Explanation for the change to procurement organisation/site 2. Detailed operational plan for the change to procurement organisation, to include:  * details of suitability of named procurement organisation/site * ‘process flow’ diagram listing all relevant steps in the change to procurement organisation/site and the actions taken by the authorisation holder in this regard * updated quality manual * validation master plan * additional supporting documentation as requested by the HPRA |
| T | 1. Change to organs procured by named procurement organisation/site on authorisation (*Schedule 2 Annex 1 Part 2)* |  | 1. Explanation for the change of organs procured by named procurement organisation on authorisation 2. Detailed operational plan for change of organs procured, to include:  * ‘process flow’ diagram listing all relevant steps in the change of organ procured and the actions taken by the authorisation holder in this regard * updated quality manual * validation master plan * additional supporting documentation as requested by the HPRA |
| T | 1. Change to the transplantation centre at which transplant activities are carried out by or in co-operation with, the authorisation holder (*Schedule 2 Annex 1 Part 3)* |  | 1. Explanation for change to transplantation centre at which transplant activities are carried out by, or in co-operation with, the authorisation holder 2. Detailed operational plan for the change to transplantation centre to include:  * details of suitability of named transplantation centre * ‘process flow’ diagram listing all relevant steps in the change of transplantation centre and the actions taken by the authorisation holder in this regard * updated quality manual * validation master plan * additional supporting documentation as requested by the HPRA |
| T | 1. Change to the organs transplanted by named transplantation centre on authorisation *(Schedule 2 Annex 1 Part 3)* |  | 1. Explanation for change to organs transplanted by named transplantation centre on authorisation 2. Detailed operational plan for the change to organs transplanted to include:  * ‘process flow diagram listing all relevant steps in the change of organs transplanted and the actions taken by the authorisation holder in this regard * updated quality manual * validation master plan * additional supporting documentation as requested by the HPRA |
| T | 1. Change to the testing laboratory(ies) at which tests required for organ and donor characterisation are carried out by or in co-operation with authorisation holder *(Schedule 2 Annex 2 Part 1)* |  | 1. Explanation for change to the testing laboratory 2. Detailed operational plan for the change to testing laboratory(s) to include:  * ‘process flow’ diagram listing all relevant steps in the change of testing laboratory and the actions taken by the authorisation holder in this regard * additional supporting documentation as requested by the HPRA  1. If third party testing laboratory; please provide:  * contract/service level agreement in place with testing laboratory * confirmation that testing laboratory is appropriately accredited for the tests it will be performing |
| T | 1. Change to the tests performed by named testing laboratory(ies) on authorisation *(Schedule 2 Annex 2 Part 1)* |  | 1. Explanation for change to the tests performed by named testing laboratory on authorisation 2. Confirmation from the authorisation holder that the tests will be carried out in accordance with the requirements of the quality and safety framework |
| T | 1. Addition of a third party at which a prescribed activity is carried out in co-operation with the authorisation holder *(Schedule 2 Annex 2 Part 2)* |  | 1. Explanation for the addition of third party at which a prescribed activity is carried out in co-operation with the authorisation holder 2. Detailed operational plan for the addition of a third party, to include:  * ‘process flow’ diagram listing all relevant steps in the addition of third party and the actions taken by the authorisation holder in this regard * copy of contract/service level agreement between the authorisation holder and the third party * confirmation that a satisfactory audit of the third party has been, or is scheduled to be performed, by the authorisation holder or appropriate designee * additional supporting documentation as requested by the HPRA |
| A | 1. Deletion of a third party at which a prescribed activity is being carried out in co-operation with the authorisation holder *(Schedule 2 Annex 2 Part 2)* |  | Explanation for deletion of third party from authorisation and confirmation that third party will no longer be used to perform prescribed activities in co-operation with authorisation holder |
| A | 1. Change of name of a third party at which a prescribed activity is carried out in co-operation with the authorisation holder *(Schedule 2 Annex 2 Part 2)* |  | 1. Letter confirming change of name to third party at which a prescribed activity is being carried out in co-operation with the authorisation holder 2. Explanation for the change of name of third party at which a prescribed activity is carried out in co-operation with the authorisation holder |
| T | 1. Change of address of a third party at which a prescribed activity is carried out in co-operation with the authorisation holder *(Schedule 2 Annex 2 Part 2)* |  | 1. Letter confirming change of address of third party at which a prescribed activity is being carried out in co-operation with the authorisation holder 2. Confirmation that a satisfactory audit/assessment of the impact of the change of address of third party, to the prescribed activity carried out, has been, or is scheduled to be performed, by the authorisation holder or appropriate designee 3. Additional supporting documentation as requested by the HPRA |
| T | 1. Change in the prescribed activity being carried out by a third party in co-operation with the authorisation holder *(Schedule 2 Annex 2 Part 2)* |  | 1. Explanation for change to prescribed activity being carried out by a third party in co-operation with the authorisation holder 2. Detailed operational plan for the change in prescribed activity carried out by a third party in co-operation with the authorisation holder, to include:  * ‘process flow’ diagram listing all relevant steps in the change of prescribed activity and the actions taken by the authorisation holder in this regard * additional supporting documentation as requested by the HPRA  1. Updated contract/service level agreement between the authorisation holder and the third party |
| T | 1. Change of responsible person on the authorisation *(Schedule 2 Annex 3)* |  | 1. Explanation for change to responsible person 2. Confirmation that new responsible person meets the requirements of S.I. 325 of 2010 3. CV of RP to be added to authorisation |
| T | 1. Change in delegate responsible person on the authorisation |  | 1. Explanation for change to delegate responsible person 2. Confirmation from RP that delegate is suitable qualified or trained, and competent to perform the duties delegated to them 3. CV of delegate RP to be added to authorisation |
| T | 1. Other change/variation. Please specify: |  | 1. Updated quality manual if applicable 2. Appropriate validation data if applicable 3. Other information as requested by HPRA |

|  |  |
| --- | --- |
| 2.2 PROPOSED WORDING  Please specify the precise present wording in the current organ 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** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| 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. | |

|  |
| --- |
| 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 organs 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**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (Applicant)  **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)