Application for Authorisation under the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012 (S.I. No. 325 of 2012)

|  |
| --- |
| 1. Application Details |
| * 1. ORGANISATION AND APPLICANT DETAILS   Name of organisation:  Address of organisation:  Applicant name:  Applicant address *(if different from organisation address)*:  Applicant phone number:  Applicant e-mail address:  Date of application: |
| * 1. OTHER LICENCES/AUTHORISATIONS HELD   (This is relevant only to other licences/authorisations granted by the Health Products Regulatory Authority.)  Name and address of licensed/authorised establishment:  Licence/authorisation number: |
| 1. Scope of Application |
| * 1. ACTIVITIES PERFORMED BY ORGANISATION  |  |  | | --- | --- | | **Activity** | **Please tick** | | Procurement of human organs for transplantation only |  | | Transplantation of human organs only |  | | Procurement and transplantation of human organs |  | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| * 1. ORGANS WHICH ARE PROCURED AND/OR TRANSPLANTED BY ORGANISATION   Please list the organs which are procured and/or transplanted by the organisation:   |  |  | | --- | --- | | **Procured** | **Transplanted** | | **1.** | **1.** | | **2.** | **2.** | | **3.** | **3.** | | **4.** | **4.** | | **5.** | **5.** | |
| * 1. PRESCRIBED ACTIVITIES TO BE AUTHORISED   ‘Prescribed activity’ means any activity relating to the donation, testing, characterisation, procurement, preservation, transport or transplantation of organs intended for transplantation to the human body.   * + 1. Procurement  |  |  |  | | --- | --- | --- | | **Prescribed activity** | **Please tick** | **Name and address of site where prescribed activity occurs** | | Donation |  |  | | Testing |  |  | | Characterisation |  |  | | Procurement |  |  | | Preservation |  |  | | Transport  (including organisation of transport) |  |  |  * + 1. Transplantation  |  |  |  | | --- | --- | --- | | **Prescribed activity** | **Please tick** | **Name and address of site where prescribed activity occurs** | | Characterisation |  |  | | Preservation |  |  | | Transport  (including organisation of transport) |  |  | | Transplantation |  |  |   Please include any additional relevant information relating to the above activities as required: |

|  |
| --- |
| 1. Additional Information |
| * 1. TESTS REQUIRED FOR DONORS OF HUMAN ORGANS FOR TRANSPLANTATION   ‘Donor Characterisation’ means the collection of the relevant information on the characteristics of the donor needed to evaluate his or her suitability for organ donation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation.  ‘Organ Characterisation’ means the collection of the relevant information on the characteristics of the organ needed to evaluate its suitability, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation.  The Annex to Directive 2010/53/EU defines the minimum and complementary datasets to be collected and retained for each donation. This includes information which allows for the characterisation of the donor and the organ in line with the definitions above. This includes a number of laboratory tests for the assessment of the functional characterisation of the organ and the detection of potentially transmissible diseases.  In the table below, please provide:   * the name and address of the laboratory(ies) that carry out any tests on behalf of the applicant organisation which may be relevant as described above; * the tests that are performed by each laboratory on behalf of the applicant organisation e.g. HIV, HCV, HBV, HLA Typing, Crossmatching etc.  |  |  |  |  | | --- | --- | --- | --- | | **Name of laboratory** | **Address of laboratory** | **Tests performed by laboratory** | **Accreditation status** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  |   Please include any additional relevant information relating to the above activities as required: |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| * 1. RELATIONS WITH THIRD PARTIES   Procurement organisations or transplantation centres should establish written agreements with a third party each time an external activity takes place which influences the quality and safety of organs for human application procurement and/or transplanted.  In the table below, please:   * provide the name(s) and address(es) of the third party(ies) that undertake such an activity(ies). * specify the activity/process, which is undertaken by the above named third party(ies). * specify the organ to which each activity relates.   The following are examples:  *Name and address of third party: National Organ Procurement Service*  *Prescribed activity/process:* *Donor characterisation*  *Organ to which prescribed activity/process applies:* *Pancreas*  *Name and address of third party: National Virus Reference Laboratory*  *Prescribed activity/process:* *Infectious marker testing of donors*  *Organ to which prescribed activity/process applies:* *Heart*   |  |  |  | | --- | --- | --- | | **Name and address of third party** | **Prescribed activity/process** | **Organs to which prescribed activity/process applies** | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  |   Please include any additional relevant information relating to the above activities as required: |
| * 1. LIST OF ADDITIONAL TRANSPLANTATION CENTRES SUPPLIED BY THE APPLICANT ORGANISATION   ‘Transplantation centre’ means a healthcare establishment, a team or a unit of a hospital or any other body which undertakes the transplantation of organs.  In the table below, please provide a list of additional transplantation centres which may be supplied by the applicant organisation.  Please note this may only be relevant to the National Organ Procurement Service; however, please indicate if you have ever provided or intend to provide other transplantation centres with organs which were primarily procured for use at your organisation.   |  |  | | --- | --- | | **Name of organisation** | **Address of organisation** | |  |  | |  |  | |  |  | |  |  |   Please include any additional relevant information relating to the above activities as required: | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| * 1. RESPONSIBLE PERSON   ‘Responsible Person’ (RP) means the person who has been designated pursuant to Regulation 11 of the European Union (Quality and Safety of Human Organs intended for Transplant) Regulations (S.I. No. 325 of 2012) as the responsible person for the organisation (procurement organisation or transplantation centre) where activities which fall within the scope of these Regulations are undertaken.  Please provide the name and contact details for the Responsible Person:  Name of RP:  Contact address:  E-mail:  Telephone:  Fax:  Qualifications:  Please provide the name and contact details for any additional delegated RP(s).   |  |  |  | | --- | --- | --- | | **Name of additional delegated RP (s):** |  |  | | **Contact address:** |  |  | | **E-mail:** |  |  | | **Telephone:** |  |  | | **Fax:** |  |  | | **Qualifications:** |  |  |   Please specify the functions that have been delegated to the above person(s):    Attach the *curriculum vitae* (CVs) of the above named RP and additional delegated RP(s).  Tick to confirm attached |

|  |
| --- |
| 1. Declaration |
| In the event of the authorisation being granted, I undertake to ensure fulfilment of the obligations arising by virtue of the terms and conditions of the authorisation and declare that the above particulars are, to the best of my knowledge and belief, correct.  **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**  (Responsible Person)  **Print name**:       **Title/position:**  **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**  (CEO/Medical Director)  **Print name**:       **Title/position:** |

Send to:

Compliance Department

Health Products Regulatory Authority

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Tel: + 353 1 676 4971

Fax: + 353 1 676 7836

E-mail: [compliance@hpra.ie](mailto:compliance@hpra.ie)