**Application form to replace the Designated Individual on an existing HTA Human Application licence**

Please complete this form if you need to replace the Designated Individual (DI) on an existing HTA Human Application licence.

Any person making an application for the role of DI on an HTA licence should be aware that under paragraph 7(2)(b), (e) and (g) of Schedule 3 of the Human Tissue Act 2004 (as amended by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)), the Human Tissue Authority may revoke a licence if it:

(a) is satisfied that the DI has failed to discharge, or is unable because of incapacity to discharge, the duty under section 18 of the Human Tissue Act 2004 and Regulation 12 of the 2007 Regulations;

(b) ceases to be satisfied that the premises specified in the licence, or any third party premises in relation to the licence, are suitable for the licensed activity;

(c) ceases to be satisfied that the DI is a suitable person to supervise the licensed activity; or

(d) is satisfied that there has been a material change of circumstances since the licence was granted.

Please note, as per Schedule 3, 8(1) of the Human Tissue Act, this form must be submitted by the Licence Holder / Licence Holder contact, following completion (including of the declaration) by the proposed DI.

Please return this application form by email to [licensing@hta.gov.uk](mailto:licensing@hta.gov.uk)

|  |  |
| --- | --- |
| Licence number |  |
| Establishment name |  |
| Establishment address | Postcode: |
| Name of current DI |  |
| Name of Licence Holder (LH) or Corporate Licence Holder (CLH) |  |
| Date variation required from |  |

**Details of proposed Designated Individual**

|  |  |
| --- | --- |
| Title |  |
| Forenames |  |
| Surname |  |
| If you have been known by another name, please give details |  |
| Email |  |
| Telephone |  |
| Job title |  |
| Correspondence address, if different from licensed premises | Postcode: |
| Have you ever applied to be a DI for another establishment? | Yes  No  If yes, please provide the establishment name and licence number. |
| Please explain the reason for the proposed change of DI |  |
| Educational and/or professional qualifications |  |
| Membership of relevant professional bodies and registration numbers where applicable |  |
| Details of any other relevant experience, including practical experience which is directly relevant to the activity authorised by the licence |  |
| With regard to the organisational structure of the establishment, please indicate your lines of responsibility with any persons working under the licence |  |
| Please explain your involvement in ensuring that staff who will work under the licence are appropriately qualified and trained in techniques relevant to their work and that they are continuously updating their skills |  |
| Please explain your involvement in governance and quality management activities within the establishment |  |
| Please provide any other information that is relevant to your suitability to fulfil the role of DI |  |

**Declaration by proposed Designated Individual**

I understand and accept the terms and conditions under which a licence is granted and varied under the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), particularly my duties under Section 18 of the Human Tissue Act 2004 and Regulation 12 of the 2007 Regulations and confirm:

|  |  |
| --- | --- |
| a) I will follow guidance issued by the Human Tissue Authority and as amended from time to time, such as the HTA’s Codes of Practice and the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment. | Yes  No |
| b) The licensed activity will be carried out under my supervision. | Yes  No |
| c) I accept I am responsible for securing that the other persons to whom the licence applies are suitable persons to participate in the carrying out of the licensed activity. | Yes  No |
| d) I accept that I am responsible for securing that suitable practices are used by the persons under my supervision in the course of carrying out the licensed activity. | Yes  No |
| e) I accept that I am responsible for compliance with the conditions of the licence. | Yes  No |
| f) I accept that I, the Licence Holder and the establishment must comply with any Directions issued by the Human Tissue Authority from time to time. | Yes  No |
| g) I acknowledge that the requirements of any Directions issued by the Human Tissue Authority from time to time represent suitable practices in the course of carrying on the licensed activity. | Yes  No |
| h) I accept that I am responsible for compliance with the conditions of any and all third party agreements entered into by, or on behalf of, the Licence Holder in relation to the licensed activity authorised to be carried out under my supervision. | Yes  No |
| i) I accept that I am responsible for securing compliance with the requirements of Regulation 13(1) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) regarding Information and Confidentiality. | Yes  No |
| j) The information provided in this form is true and accurate to the best of my knowledge. | Yes  No |
| k) I consent to be the Designated Individual for the licence referred to in this application. | Yes  No |
|  |  |
| Name: | Date: DD/MM/YYYY |