**Application form for a change of premises**

**for establishments in the Human Application sector**

This application form can be used by establishments that already hold a licence in the Human Application sector wishing to make a change to their licensed premises.

**The DI or LH will be required to submit this application form by email to** licensing@hta.gov.uk

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| **Establishment information** |
| An application for a change of premises of a licensed establishment must specify the new address where the activities are to take place. Where a change of premises is required for more than one site (i.e. a satellite site), this will need a separate application form. |
| Licence number |  |
| Name of Designated Individual |  |
| Premises name |  |
| Department |  |
| New Address | Postcode: |
| Proposed date of relocation or change |  |

In the following section, please carry out a self-assessment for all HTA standards based on the proposed new premises and provide examples of compliance as required.

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| **PFE1 – The premises are fit for purpose.** |
| a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| b) There are procedures to review and maintain the safety of staff, visitors and patients. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| c) The premises have sufficient space for procedures to be carried out safely and efficiently. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of the deceased. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| e) There are procedures to ensure that the premises are secure and confidentiality is maintained. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment’s medical and scientific activities. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |

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| **PFE2 –** **Environmental controls are in place to avoid potential contamination.** |
| a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 001/2021. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| c) There are procedures for cleaning and decontamination. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |

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| **PFE3 - There are appropriate facilities for the storage of tissues and / or cells, consumables and records.** |
| a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| b) There are systems to deal with emergencies on a 24 hour basis. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| d) There is a documented, specified maximum storage period for tissues and / or cells. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |

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| **PFE4** – **Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.** |
| a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 001/2021. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| d) Records are kept of transportation and delivery. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| h) Packaging and containers used for transportation are validated to ensure they are fit for purpose. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |

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| **PFE5 –** **Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.** |
| a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| b) Critical equipment is maintained and serviced in accordance with the manufacturer’s instructions. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| d) New and repaired equipment is validated before use and this is documented. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| e) There are documented agreements with maintenance companies. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| g) Instruments and devices used for procurement are sterile, validated and regularly maintained. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| i) Staff are aware of how to report an equipment problem. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| j) For each critical process, the materials, equipment and personnel are identified and documented. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| k) There are contingency plans for equipment failure. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |