**Guidance for how to add a Satellite Site to a licence under the Human Tissue (Quality and Safety for Human Application) Regulations 2007**

Satellite sites are premises that are under the same governance processes as the main licensed establishment (the hub) and are supervised by the same Designated Individual (DI). The DI at the hub must have systems in place to ensure that the governance framework is properly implemented across all premises which are on the licence. The DI should plan to make regular visits to satellites to verify that the licensing framework, systems and processes are working in practice. The DI must ensure compliance with the conditions of the licence at these satellite establishments and the Licence Holder must accept responsibility paying the associated licensing fees.

The DI and Licence Holder at the main premises must agree to take responsibility for the systems and processes in place at the satellite site and supervise those activities. This is to ensure compliance with the licensing framework at the satellite site. Thus the satellite sites are accountable to the DI at the main site.

There must be a Person Designated at each satellite site who can direct activities that are licensed there and who is accountable to the DI at the hub. The Human Tissue Authority will send the licences and related correspondence to the DI at the hub to acknowledge it is appropriate for the activity taking place at the satellite site to appear on the hub licence. The DI is required to provide any additional information that may be requested by the Human Tissue Authority regarding satellite sites working under their supervision.

If the satellites are as large as the hub and/or are providing the same activities, the complexity of the services provided is increased. This means that a more hands-on approach with a DI on site (rather than the premises being a satellite site) may be more appropriate to ensure compliance with licence activities. The Human Tissue Authority will review the information provided on this application form to make a judgement whether a satellite licence is or is not appropriate.

Please return this form by email to licensing@hta.gov.uk

**Application form under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 to add a Satellite Site to a licence**

One form to be completed for each satellite site.

To be completed by the Licence Holder or Designated Individual.

|  |  |
| --- | --- |
| Licensed establishment name (hub) |  |
| Licence number |  |
| Name of satellite premises |  |
| Address of satellite premises where licensed activity is to take place | Postcode: |
| **Activity(ies) to be licensed at the satellite site** Please note these activities must be included on the licence for the hub. |
| Under the Human Tissue Act 2004 | [ ]  Section 16(2)(e) (ii) – The storage of relevant material which has come from a human body for use for a Scheduled Purpose other than transplantation |
| Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 | [ ]  Procurement [ ]  Testing[ ]  Processing [ ]  Storage[ ]  Distribution[ ]  Import[ ]  Export  |

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Person(s) Designated at satellite site | Job title | Email address | Telephone number |
| Primary: |  |  |  |
| Additional: |  |  |  |
| Additional: |  |  |  |
| When did the satellite become operational? (approximate date) |  |
| Is the satellite under the same governance as the main hub? | Yes [ ]  No [ ]  |
| Please explain how the satellite site links to the governance of the hub |  |
| To assist the Human Tissue Authority, please provide a short synopsis describing the activities carried out at the satellite on behalf of the establishment |  |
| How does the DI intend to supervise the activities at the satellite site? |  |
| How many staff are involved in carrying out the licensable activity in the satellite site? |  |

|  |  |
| --- | --- |
| Please explain what responsibilities the staff at the satellite site have for meeting the consent requirements of the Human Tissue Act and Codes of Practice |  |
| Does the satellite store relevant material on behalf of any organisation other than the hub? | Yes [ ]  No [ ] If yes, please provide details. |
| Please state how many adverse events have occurred at the satellite in the last year |  |
| Does the satellite have any form of accreditation, such as CPA, MHRA, JACIE, ISO etc?  | Yes [ ]  No [ ] If yes, please provide the following information for each accreditation:Accrediting body:Date accreditation obtained:Current status:Any further information: |

|  |  |  |  |
| --- | --- | --- | --- |
| For each tissue type please state how many units on average are procured, processed, stored, distributed and imported / exported by the satellite each year.Please continue on a separate sheet if necessary. | **Tissue type:** | **Usage:** | **Average number of units:** |
|  | Procured |  |
| Processed |  |
| Stored |  |
| Distributed |  |
| Imported |  |
| Exported |  |
|  | Procured |  |
| Processed |  |
| Stored |  |
| Distributed |  |
| Imported |  |
| Exported |  |
|  | Procured |  |
| Processed |  |
| Stored |  |
| Distributed |  |
| Imported |  |
| Exported |  |
|  | Procured |  |
| Processed |  |
| Stored |  |
| Distributed |  |
| Imported |  |
| Exported |  |
| Please provide any additional information you feel may be relevant to this application |  |
| Name of person who completed this form (must be either the Licence Holder or Designated Individual from the hub): | Date: DD/MM/YYYY |