**Guidance on how to add a Research** [**Satellite Site**](http://www.hta.gov.uk/licensingandinspections/satellitepremises.cfm) **to a licence under the Human Tissue Act 2004**

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 (LH) must accept responsibility for paying the associated licensing fees.

The DI and LH 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.

Persons Designated (PDs) support the DI in overseeing activities under the licence to ensure compliance. There must be a named PD at each satellite. We 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 us 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. We 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 Act 2004 to add a Research 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: |
| Licensable activity(ies) taking place at the satellite – please note this must be on the licence application for the hub | [ ]  Section 16(2)(c) – The removal from the body of a deceased person of relevant material of which the body consists or which it contains for use of a Scheduled Purpose other than transplantation (where removal is not in the course of a post mortem examination) [ ]  Section 16(2)(e) (ii) – The storage of relevant material which has come from a human body for use for a Scheduled Purpose |

|  |  |  |  |
| --- | --- | --- | --- |
| Name(s) 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 site? | 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. |
| Does the satellite supply or use relevant material for research purposes? | Yes [ ]  No [ ]  |
| 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 (UKAS, 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: |
| 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 |

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

|  |
| --- |
| **PFE1 – The premises are secure and fit for purpose.** |
| a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| c) There are documented cleaning and decontamination procedures. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |

|  |
| --- |
| **PFE2 – There are appropriate facilities for the storage of bodies and human****tissue.** |
| a) There is sufficient storage capacity. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| b) Storage arrangements ensure the dignity of the deceased. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| c) Storage conditions are monitored, recorded and acted on when required. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| d) There are documented contingency plans in place in case of failure in storage area. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |

|  |
| --- |
| **PFE3 – Equipment is appropriate for use, maintained, validated and where****appropriate monitored.** |
| a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| b) Users have access to instructions for equipment and are aware of how to report an equipment problem. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |
| c) Staff are provided with suitable personal protective equipment. |
| Not applicable [ ]  Not met [ ]  Met [ ]  |
| **Please provide examples:** |

**Please submit the following documents as part of your satellite application:**

Please note that your application will not be processed unless you submit all of the documents below. If you are unable to provide any of the documents, please explain why.

|  |
| --- |
| **Research Satellite Application Checklist – Mandatory documents** |
| **Premises, Facilities and Equipment** |
| [ ]  | Risk assessment of premises |
| [ ]  | Site plan, indicating where storage of relevant material will take place |
| [ ]  | Information on storage facilities that are/will be available (e.g., number of freezers, fridges, room temperature storage) |
| [ ]  | Contingency plan for failure in storage area |
| [ ]  | SOPs for monitoring and testing of storage conditions |

Further information on documentation

|  |
| --- |
|  |