Vendor Oversight Plan

**Vendor Information:**

|  |  |
| --- | --- |
| **Name of Vendor** | Vendor Name:  Address : |
| **Contracted Service to be provided** | Services will be to provide XXX for the study. |
| **Sponsor Study Number/Abbrev Title** |  |
| **Clinical Project Manager** |  |
| **Executed Contract Date** |  |
| **Oversight Plan Owner** | Usually the CPM |

**Contact Information:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sponsor Contact Information** | | | |
|  | **Name/Role** | **Telephone number** | **Email** |
| **Primary** |  |  |  |
| **Secondary** |  |  |  |
| **Vendor Contact Information** | | | |
|  | **Name/Role** | **Telephone number** | **Email** |
| **Primary** |  |  |  |
| **Secondary** |  |  |  |

**Supporting and Associated Documents:**

|  |  |
| --- | --- |
| **Details of the Original Contract** | The Contract used was based on a Sponsor/Vendor template (delate as applicable) and was executed on (add date). |
| **Other required documents**  (e.g., CDAs, technical/quality agreements for drug manufacture etc) | The following documents are applicable to the contracted services that the Vendor (XXX) is to provide:   1. X 2. Y 3. Z |
| **Documentation of Training** | Site staff training will be documented in SIV report/s and on the study level training log. |

**SOPs and Training:**

|  |  |
| --- | --- |
| **Details of applicable SOPs**  (or location of the list) | Per the Contract the Vendor (XXX) will follow local internal SOPs that are maintained at their facility as well as working to Good Clinical Practice. There are no Sponsor/R&D SOPs being used by this Vendor for this study. |
| **Details of Training**  (format, frequency) |  |
| **Documentation of Training** | Site staff training will be documented in SIV report/s and on the study level training log. |

**Communication Plan:**

|  |  |
| --- | --- |
| **Meeting Type, Frequency, Documentation** | XXX will have regular teleconferences with the Sponsor study team. The Sponsor is responsible for preparing the agenda and authoring the meeting minutes which will be distributed by email. |
| **Location of correspondence**  (meeting minutes, emails etc) | TMF |
| **Other Communication Expectations** | Ongoing communication is expected as needed between the Sponsor study team and XXX via email/telephone. Teleconferences will be scheduled on demand to sort immediate issues, any need for clarifications or decision making. |

**Quality Management**

|  |  |
| --- | --- |
| **Details of Site Visits**  (Planned frequency, triggers) | For Vendors that have not been contracted by the Sponsor previously, a face to face site visit is recommended ahead of the signature of Contract.  During the term of the Contract the Sponsor will visit the Vendor premises on a regular basis proportionate to the duration of the study and complexity of the Contract requirements. |
| **Details of Planned Audits**  (If applicable) | The Sponsor will conduct an audit of the Vendor if applicable. |
| **Milestones** | Milestones are outlined in the Contract and as agreed between the Sponsor and XXX during the course of the study. |
| **Quality Management of Services** | The Sponsor is to ensure all timelines set forth by the Vendor are met and that services are provided in line with the Contract.  The Vendor is responsible for all project management and quality assurance activities necessary to fulfill its obligations under the Contract. |
| **Performance and Quality Metrics** | The Vendor will provide (service being provided), within XX working days from (e.g., sample receipt).  Throughout the project, the Sponsor will conduct quality control of the data to ensure that the correct data has been received. Any discrepancies found will be resolved directly with the Vendor or escalated as appropriate. |
| **Location of Quality Management Documentation** | TMF |

**Resolution of Issues:**

|  |  |
| --- | --- |
| **General Issue Communication Process** | XXX will promptly notify the Sponsor of any unforeseen events that occur during performance of Services that may affect the cost, quality, integrity or timelines of Services.  If Vendor performance issues are identified the study team should take the following steps:   * The Clinical Project Manager (CPM) is the primary Point of Contact to work with the Vendor to develop a corrective action plan including a timeline for resolution. * If the corrective action plan is not implemented as agreed by the Vendor the CPM will escalate the matter to the R&D QA meeting. |
| **Staff Changes/Resourcing** | The Sponsor expects to have a Vendor Primary Contact who will manage and coordinate all aspects of delivery of the XXX services to the Sponsor. The Vendor will not re-assign the performance of Services to a different member of personnel without prior written authorisation from the Sponsor. The Sponsor will not unreasonably withhold approval of such personnel changes.  Any change in the Sponsor Primary Contact will be communicated to XXX as soon as possible so that channels of communication and oversight are continuous. |
| **Performance Issues** | If Services are not being performed in accordance with the Contract, a meeting will be held with XXX to discuss and resolve issues. This meeting may be conducted as a site visit or teleconference as appropriate.  Unresolved issues will be escalated to the R&D QA Meeting. Upon non-responsiveness from the Vendor, a warning letter may be distributed detailing the issues and further remediation plans to be expected. If the Sponsor has reason to believe that Services are not being performed, or were not performed, the Sponsor may schedule an inspection or audit without advance notice to XXX. |
| **Scope Change in the Contract** | Either the Sponsor or XXX may request a modification to the original Contract/scope of activities. However, no modification will be effective unless made by means of a written Contract amendment which has been signed by both parties. |
| **Budget** | The budget and schedule of payments can be viewed in the Contract.  The CPM is to alert the PI regarding an increase or decrease in budget requirements for the Contract. |
| **Location of Issue/Resolution Documentation** | TMF |

**Document Control and History**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Date** | **Author(s)** | **Summary of Changes** |
| 1.0 |  | Melissa Duckworth | First Version |