# VENDOR OVERSIGHT PLAN

|  |  |
| --- | --- |
| **Study**  |  |
| **Protocol Number** |  |
| **Sponsor** |  |
| **Chief Investigator** |  |
| **Trial Manager** |  |
| **Version / Date** |  |

# Purpose

* 1. The Sponsor must maintain oversight of vendors which provide services in the conduct of clinical trials and ensure vendors are suitable to carry out delegated tasks. This vendor oversight plan serves as a dynamic management and instruction tool for the Sponsor and study team to oversee vendor assessment, deliverables and procedures applicable to the project.
	2. Prior to proceeding with project related work, vendors must be approved by the ACCORD QA Manager, or designee, as per ACCORD SOP QA009 (Vendor Assessment). The QA Manager, or designee, will maintain a current list of approved vendors in the ACCORD SharePoint QA files. Copies of vendor documentation will be filed in the Trial Master File (TMF) and Sponsor File.
	3. Change requests for contracted scope of work will be assessed and approved by the Sponsor and if impacted, adjustments will be made via a new version of the vendor oversight plan.

## Vendors

* 1. Vendors providing services relating to the <insert study> project have been identified at the Combined Risk Assessment (ACCORD SOP GS002) and are summarised below.
	2. Green highlight means the action has been completed or no action is required, e.g. the agreement has been signed or the vendor assessment has been completed. Yellow highlight means the details/actions are yet to be confirmed.

| Vendor Name | Services Provided | Contract Held | Vendor Assessment Method |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# Communications

| Name | Contact Name / Title | Address | Contact Details |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

* 1. The above list will be contacted by the Trial Manager as a result of new/revised Sponsor systems, processes or protocol amendments / revised study documents relevant to contracted vendors.

# Training

* 1. Listed below are training materials that the study team and investigator sites will need to review / complete for vendor system and processes. Training may not be required for every vendor used for the project.

|  |  |
| --- | --- |
| **Vendor** |  |
| **Training of system access required** |  |
| **Purpose / description** |  |
| **Party(ies) requiring training** |  |
| **Targeted timing of training / system access** |  |
| **Training delivery method** |  |

# Document History

|  |  |  |
| --- | --- | --- |
| **Version****Number** | **Effective Date** | **Reason for Change** |
| 1.0 | DD MMM YYYY |  |

# Approvals

|  |  |
| --- | --- |
| **Sign** | **Date** |
| AUTHOR:  |  |
| APPROVED:  |  |
| AUTHORISED:  |  |