**Third-Party Oversight Plan**

**Introduction**

As a leading practice for Technical Oversight, it is important to ensure that an effective oversight plan is developed and implemented for Third-Party Providers. The oversight plan should be fit-for-purpose based on the specific Provider and services that Provider delivers. Responsibility for third-party oversight of Technical Service Providers (Central Labs, IxRS, ECG providers, etc.) may be delegated to a CRO as part of the Sponsor and CRO collaboration. In that scenario, the CRO must be able to deliver and document appropriate and effective oversight of these providers. The purpose of this tool is to provide a template for developing a Third-Party Oversight Plan to enable effective oversight of Third-Party Providers and documentation of that plan.

| **Third-Party Oversight Plan** | |
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| **Oversight Leader** *(This individual is accountable for this plan and responsible for oversight of Technical Provider.)* |  |
| **Title of Oversight Leader** |  |
| **Organization Providing Oversight** | <INSERT NAME OF CRO IF OVERSIGHT IS PROVIDED BY CRO> |
| **Oversight Leader Information** | |
| **Mailing Address** |  |
| **Email Address** |  |
| **Business Phone Number** |  |
| **Mobile Phone Number** |  |
| **Fax Number** |  |
| **Administrative Assistant** |  |
| **Administrative Assistant Contact Information** |  |
| **Back Up Contact (if Oversight Leader is Absent)** |  |
| **Back Up Email Address** |  |
| **Back Up Phone Number** |  |
| **Back Up Mobile Phone Number** |  |
| **Third-Party Provider (CRO or Technical Service Provider)** | |
| **Third-Party Provider Company Name** |  |
| **Services Provided by Third-Party (CRO or Technical Service Provider)** | <Examples include traditional CRO services (e.g. monitoring, data management) or Technical Services (Central Laboratory Services, ECG Services, Imaging Services, etc.)> |
| **Project/Protocols Overseen** | Refer to project name and/or protocol numbers for which Oversight Plan applies |
| **Primary Contact at Third-Party Provider** |  |
| **Title** |  |
| **Mailing Address** |  |
| **Email Address** |  |
| **Business Phone Number** |  |
| **Mobile Phone Number** |  |
| **Fax Number** |  |
| **Administrative Assistant** |  |
| **Administrative Assistant Contact Information** |  |
| **Back Up Contact at Third-Party Provider (If Primary Contact is Absent)\_** |  |
| **Back Up Email Address** |  |
| **Back Up Phone Number** |  |
| **Back Up Mobile Phone Number** |  |
| **Contract #/Purchase Order #** |  |

| **Third-Party Provider Oversight Plan-**  **Description of Oversight Activity** | |
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| **Date of Initial Engagement as a Strategic/Preferred Provider (or if a single engagement, date of contract execution)** |  |
| **Governance Construct** | Briefly describe governance construct (committees) and provide link to governance charters via Document: Gov Tool 02a- Template for a Governance Charter |
| **Governance Contacts** | Provide link to governance contacts via Document: Comm Tool 08 - Governance Key Contacts List template |
| **Communication Plan** | Briefly describe type, frequency, format, target audience and documentation of communication and/or provide link to separate Communication Plan Document: Comm Tool 02- Communication Management Plan |
| **Recurring Oversight Meetings** | Briefly describe recurring project specific oversight meetings (refer to frequency, link to standing agendas and meeting minutes, attendee lists, etc.). |
| **Kick-Off Meeting** | Briefly describe kick-off meeting and provide link to associated documents. (Date, training, location for storage of meeting agenda, meeting minutes, attendee lists, etc.) |
| **Central Repository for Document Storage** | Briefly describe central repository and insert link |
| **Risk Management Plan and Risk Oversight Practices** | Briefly describe proactive risk management practices, intent for mitigation plan development, contingency planning, triggers for implementing contingency plans, and/or link to Risk Management Plan via Document: Risk Tool 07- Risk Management Plan Template |
| **Issue Escalation Process** | Briefly describe issue escalation at project/protocol/function level and at governance level including roles and responsibilities for general process. Describe staff performance issue management (refer to Staffing/ Onboarding section for staff change approach). Provide link to escalation contacts via Document: Comm Tool 06- Decision Escalation Process. Provide periodic review process of escalated issues and link to documentation associated with escalated issues (Documents: Comm Tool 14.2 - Issue Log Template; Comm Tool 07- Risk or Issue Communication template). |
| **IT Systems Used** | Provide list and brief description of IT systems used |
| **IT Systems Support Contact/s** | Provide contact information for IT systems: Email address, business phone, mobile phone, etc. |
| **IT Issues Management** | Briefly describe process for addressing IT systems issues (unscheduled down time, access issues, etc.) |
| **SOPs Used** | Briefly describe SOPs used and/or provide link to Document: Process Tool 03a- Process Tracking Table |
| **Training Sessions** | Briefly describe initial training completed and refresher training planned. Refer to SOP, IT systems, and other training requirements. Include dates, topics covered, location of materials, etc. Briefly describe documentation of training (location, review, etc.). Update in future versions as planned training is completed to include staff that was trained and when. |
| **Assessment Reviews or Visits** | Briefly describe oversight associated with prequalification of provider including re-assessments and frequency. Provide actual dates of assessment/s and whether they were virtual or on-site. Provide link to assessment report via Document: Process Tool 05a- Supplier Assessment Report Template. Refer to QA audits as a separate means for oversight with associated tracking and documentation; include a QA contact name for independent follow up as needed. |
| **Staffing and Onboarding of Team Members** | Briefly describe onboarding (CV review, interview/meeting, etc.) of key resources for project team. Describe staff back up expectations and staff change process including documentation of staff start and end dates |
| **Periodic Reports** | Briefly describe types of reports (e.g. project management, resource management, etc.), frequency of reports, and general content; provide link to templates for reports |
| **Metrics (KPIs, KQIs, etc.)** | Provide link to list of metrics that are tracked via Document: Met Tool 11- KPI Development Worksheet or Met Tool 18- Metrics Plan Thought Map and the location of completed metrics reports. Briefly describe review process. |
| **Deliverables Review** | Briefly describe key deliverables and review process associated with timeliness of delivery, quality (adherence to expectations/ standards), quality control reviews (midstream if applicable and final reviews). |
| **Financial Oversight** | Briefly describe periodic review of contract and scope of work. Briefly describe invoice review, payment tracking, budget review, and discrepancy management. Describe ongoing and final financial and scope reconciliation. |
| **Scope Changes** | Briefly describe process for addressing changes in scope for the project including timing for documentation of changes and timing for initiation of work |

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| **Key Document Storage** | |
| **Team Lists** | Provide link to central stored Team List/s via Document: Comm Tool 09 - Team Contact List template |
| **Provider List** | Provide list of all providers that interface with this provider and/or provide link to list of all providers used via Document: Process Tool 05c- Project Supplier Tracking Table |
| **Contract and Change Orders** | Provide link to storage location for original MSA/contract, scope of work and change orders |
| **RACI Chart** | Provide link to centrally stored RACI Charts via Document: RnR Tool 06- Template RACI Chart or Comm Tool 05 -Risk/Issue Triggers RACI Matrix template |
| **Other Key Documents** | Briefly describe and provide link/s to other key document/s |

| **Third-Party Oversight Plan**  **Revision Date** | **Description of Change** | **Revision Approver**  **(name and title)** | **Revision Signatures** |
| --- | --- | --- | --- |
| **<Insert Version Date>** | Original Oversight Plan |  |  |
| **<Insert Version Date>** |  |  |  |
| **<Insert Version Date>** |  |  |  |
| **<Insert Version Date>** |  |  |  |
| **<Insert Version Date>** |  |  |  |
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| **<Insert Version Date>** |  |  |  |
| **<Insert Version Date>** |  |  |  |
| **<Insert Version Date>** | Final Oversight Plan at time of contract closure |  |  |

For questions or additional information, please visit <http://theavocagroup.com/contact/>.