Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Site Location Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Meeting Date (DD/MMM/YY)/Start Time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Completed Notes**

|  |  |  |
| --- | --- | --- |
| **SCHEDULING the SIV** | | |
| Maintain contact with the Regulatory and Grants & Contracts teams as you move closer to IRB approval and execution of the study contract. **The SIV may not be scheduled until the CTA is fully executed and IRB approval is received.** |  |  |
| Speak with the study sponsor and/ or PI to determine:   * Is a conference room with projector, phone, internet or other audiovisual aids needed? * Can the SIV be conducted via WebEx, Zoom and/or any other remote viewing electronic system? * What is the time commitment required for the attendees? * Who should be in attendance? * Will a tour of the study facilities be necessary? And if so, what? |  |  |
| Discuss what, if any, other non-research departments will need to be involved with or trained on the study. Are there specific infusion, pathology, surgical or imaging or other needs? If so, determine:   * Is it more efficient to invite a representative from the department to the SIV? * Is it more efficient to hold a study specific training within the department after the SIV and before the first patient is enrolled on the study? |  |  |
| Once the above-mentioned details have been confirmed: Send an invitation to **all** attendees (including the PI, Sub-Is, and their administrative assistants to make sure it is on everyone’s calendar.)  It is also acceptable to send a list of attendees to the sponsor and request the sponsor send out the initial invitation. |  |  |
| **A WEEK BEFORE THE SIV** | | |
| Confirm the SIV location and provide detailed instructions on how to get to the location or the log-in information regarding the meeting.  Arrange for someone to escort any sponsor representatives to the SIV meeting location. Make sure there is a point person that can use the audiovisual equipment, as applicable. |  |  |
| Obtain the SIV agenda from the study sponsor representative. |  |  |
| Obtain any study materials from the designated study staff member or study sponsor representative. Distribute them to attendees so they can review the information prior to the SIV and compose any questions or document any concerns for discussion during the SIV. |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Protocol:**  **Principal Investigator:** | **In Progress** | **Completed** | **Notes** |

|  |  |  |  |
| --- | --- | --- | --- |
| **CONDUCTING the SIV** | | | |
| **REGULATORY:** | | | |
| Confirm who is taking attendance during the meeting. If it is the sponsor taking attendance, be sure to request a copy of their attendance log. |  |  |  |
| Confirm all key study personnel have the necessary training and access to fulfill the study requirements to which they are assigned (i.e. applicable CITI certification(s), IATA EDC, EMR, etc.). |  |  |  |
| Discuss the processes and timelines for submission of research billing/invoices, per the fully executed CTA. |  |  |  |
| Discuss any participant compensation and the reconciliation of this information on any logs or in any study specific systems (Tango, Greenphire, parking or meal vouchers, etc.). |  |  |  |
| **RECRUITMENT:** | | | |
| Confirm locations where enrollment will occur, study visits will be conducted. Discuss staff logistics of executing study procedures at those locations. |  |  |  |
| **INVESTIGATIONAL PRODUCTS (if applicable):** | | | |
| Review the test article storage, dosage(s), dispensation, accountability, IB(s), Package Insert(s), and destruction or return processes. Review receipt and inventory of drug shipments, |  |  |  |
| Review IXRS access and blinding/unblinding procedures. Will there be anything normally outside the scope of the SOPs IDS has in place? |  |  |  |
| **SAMPLE PROCESSING AND SHIPPING, EQUIPMENT:** | | | |
| Review laboratory manuals and specimen procedures, shipping costs, requirements and certifications, specimen tracking if applicable. |  |  |  |
| Review receipt and inventory of any expected study related equipment or supplies. |  |  |  |
| Review any additional manuals and guidance documents for study equipment or procedures (ECG, Imaging, etc.).  Confirm if there is any training needed outside of this SIV for those items. |  |  |  |
| Identify if any outside vendor systems will be used. Confirm if there is any training needed outside of this SIV to gain access. |  |  |  |
| **Protocol:**  **Principal Investigator:**  **Date:** | **In Progress** | **Completed** | **Notes** |
| Review the protocol-specific source documents and/or case report forms to be used during the study |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **PROTOCOL:** | | | |
| Confirm the current version of the protocol |  |  |  |
| Confirm the version of the protocol the study will open under |  |  |  |
| Are amendments expected in the near future? |  |  |  |
| Review study objectives |  |  |  |
| Review time and events schedule |  |  |  |
| Review inclusion and exclusion criteria |  |  |  |
| Review informed consent process |  |  |  |
| Review patient enrollment/randomization processes and procedures |  |  |  |
| Review the risks associated with study participation and the steps to minimize any potential risks to study participation. |  |  |  |
| Discuss the event reporting requirements and ensure a study communication plan is in place. |  |  |  |
| **DATA MANAGEMENT:** | | | |
| Review the data and record keeping plan and ensure all study staff has access to, and training for, the data capture tools and systems, as applicable. |  |  |  |
| **MONITORING PLAN:** | | | |
| Review the monitoring plan, internal QA/QC plans, the DSMB, etc. |  |  |  |
| Review the sponsor contacts information. Will a CRO be used? |  |  |  |
| **AFTER the SIV** | | | |
| Request meeting minutes from sponsor regarding the SIV discussion. |  |  |  |
| Ensure the SIV signature sheet to document attendance/training and the completed Delegation Log are kept on file. |  |  |  |
| Ensure anyone who was unable to attend the SIV is trained prior to having any involvement in the study. Add them to the Delegation Log after their training is documented. |  |  |  |
| Make sure all outstanding questions or concerns are addressed prior to the first participant placed on study. |  |  |  |
| Make sure all essential documents are filed and the sponsor has received any documents they’ve requested |  |  |  |
| Schedule a meeting with finance/accounts payable and scheduling/insurance auth. Review the coverage analysis, billing guide, requirements, and expectations prior to first enrollment. |  |  |  |