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

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| **SCHEDULING the SIV** | | |
| Maintain constant contact with the Regulatory and Grants & Contracts teams as you move closer to IRB approval and execution of the study contract. Begin planning the date of the site initiation visit (SIV). |  |  |
| Speak with the study sponsor and/ or PI to determine what the agenda for the SIV will be and the attendance requirements for key personnel:   * Is a conference room with projector, 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 all be in attendance? * Will a tour of the study facilities be necessary? And if so, what? |  |  |
| Once the above-mentioned details have been confirmed: Send an Outlook invitation to all attendees (including the PI, the sub- investigators and their administrative assistants, and if applicable, Investigational Drug Services representative, research nurses research coordinators, regulatory and data specialist, etc.) to make sure it is on everyone’s calendar. |  |  |
| **A WEEK BEFORE THE SIV** | | |
| Confirm with that everything is a “GO” for the SIV, confirm the SIV location for internal or external attendees and either provide detail instructions how to get to the location or the log-in information regarding the meeting venue or arrange for someone to escort, for example, the sponsor representatives or study staff to the SIV meeting location and make sure there is a point person that can use the audiovisual equipment, as applicable. |  |  |
| Draft or obtain the SIV agenda from the designated study staff member or study sponsor representative. |  |  |
| Copy or obtain any study materials from the designated study staff member or study sponsor representative that will be used during the SIV so attendees can review the information prior to the SIV and compose any questions or document any concerns for discussion during the SIV. |  |  |
| Prepare a staff signature sheet to document SIV training for the study records. |  |  |

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| **CONDUCTING the SIV** | | | |
| **REGULATORY:** | | | |
| Confirm that the Delegation of Authority Log is completed with all key study personnel and that they are IRB approved to participate in the study and their delegated tasks are with their Scope of Practice. |  |  |  |
| Confirm that all key study personnel have, as applicable, the necessary training and access to fulfill the study requirements to which they are assigned (i.e. CITI CREC certification, CITI GCP certification, Investigator Training, Research Orientation, IATA certification, EDC/EDC certification, EMR access (inpatient and/or ambulatory/outpatient etc.). |  |  |  |
| Discuss the maintenance of the coverage analysis spreadsheet and timelines for submission of the research billing notification forms (RBNF). |  |  |  |
| Discuss the disposition of any participant compensation and the reconciliation of this information on any logs or in any study specific systems i.e. gift cards, cash, checks, gifts, parking or meal vouchers, etc. |  |  |  |
| **RECRUITMENT:** | | | |
| Confirm the UH locations where enrollment will occur, study visits will conducted and discuss the study staff logistics of executing study procedures at those locations. |  |  |  |
| Review the inventory of supplies with all departments involved in the study. |  |  |  |
| **INVESTIGATIONAL PRODUCTS:** | | | |
| Review the test article storage, dispensation, documentation and use of Investigational Drug Services, if applicable. |  |  |  |
| **SAMPLE PROCESSING AND SHIPPING:** | | | |
| Review the Manual of Procedures (MOP), including all laboratory and specimen procedures, shipping requirements, and validations and certifications, if applicable. Also, review the Z-req. |  |  |  |
| Review the protocol-specific source documents and/or case report forms to be used during the study |  |  |  |

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| **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 the study objectives |  |  | |  | |
| Review the time and events schedule |  |  | |  | |
| Review the inclusion and exclusion criteria |  |  | |  | |
| Review the informed consent process; perform a mock informed consent discussion to ensure it is appropriately executed and consenters can answer questions and/or determine who should present this information. |  |  | |  | |
| 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 (source, CRFs, REDCap, OnCore, etc.) and ensure all study staff has access to and training with the data capture tools and systems, as applicable. |  |  | |  | |
| **MONITORING PLAN:** | | | | | |
| Review the monitoring plan, internal QA/QC plans, the DSMB, etc. |  |  | |  | |
| **AFTER the SIV** | | | | | |
| Compose meeting minutes regarding the SIV discussion. |  |  | |  | |
| Ensure the SIV signature sheet to document attendance and the completed (signed, initialed and dated) Delegation Log are kept on file. |  |  | |  | |
| Make sure all outstanding questions or concerns are addressed prior to the first participant placed on study. |  |  | |  | |
| Make sure all essential documents (CVs, licenses and certifications) are on file. |  |  | |  | |