**Study Operation Planning Tips**

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| **Finalize Contract and Budget** |
| The UMMC Office of Clinical Trials (OCT) negotiates and executes contracts as well as negotiates budgets. Be sure to forward the budget, contract, consent document, protocol, and any other documents received from sponsors to OCT. |
| NOTES: Click or tap here to enter text. |
| **Define Roles and Responsibilities** |
| Be sure to define the roles and responsibilities of all study personnel. Who is the study coordinator? Who is the regulatory contact? |
| NOTES: Click or tap here to enter text. |
| **Confirm Research Support Services and Facilities** |
| Based upon your final budget and contract, contact the appropriate support services, such as pharmacy and lab, to let them know that you are ready to utilize services. |
| NOTES: Click or tap here to enter text. |
| **Identify Resources Available** |
| Identify resources available to optimize efficiency in the coordination of a study.   * EPIC – Electronic Medical Record (EMR)   + [Access Request](https://workflow.umc.edu/access/) * RedCap – HIPAA compliant Electronic Data Capture System (EDC)   + [More Information](https://intranet.umc.edu/Research/Centers%20and%20Institutes/Center%20for%20Informatics%20and%20Analytics/REDCap/REDCap.html) * IDEATE – Institutional Review Board (IRB)   + [More Information](https://intranet.umc.edu/Research/Ideate%20-%20External%20Site.html) * Velos eReserach   + More information to come once Velos is implemented later in 2020.   In addition, submit any access request and complete any required training. |
| NOTES: Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Protocol No./ Version and Date** |  |
| **Name of Study** |  |
| **Name of Sponsor** |  |
| **Name of Investigator** |  |
| **Name of Site/ Site Number** |  |

**Site Initiation Visit Checklist**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Are you ready for the site initiation visit?** *This checklist will help you to prepare.* | | | | |
| **Confirm information provided by the sponsor** | | | | |
|  | **Yes** | **No** | **N/A** | **Comments** |
| Final contract and budget signed and filed |  |  |  |  |
| Protocol received |  |  |  |  |
| **Clinical study regulatory requirements** | | | | |
|  | **Yes** | **No** | **N/A** | **Comments** |
| IRB approval, as well as any other UMMC required ancillary approvals (e.g. Radiation Safety and Biosafety), has been granted for the study |  |  |  |  |
| Protocol reviewed by Investigator and staff |  |  |  |  |
| Good Clinical Practice (GCP), IRB, and other regulatory requirements have been reviewed |  |  |  |  |
| **Study management and record-keeping requirements** | | | | |
|  | **Yes** | **No** | **N/A** | **Comments** |
| Particular roles and responsibilities of the staff have been determined |  |  |  |  |
| All materials and documents for the study have been received and secretly stored |  |  |  |  |
| Study file prepared (e.g. dated curriculum vitae, contract, protocol, source documents, communication/site visit logs, product logs, and relevant correspondences from IRB, FDA, etc.) |  |  |  |  |
| **Study Supplies and Miscellaneous** | | | | |
|  | **Yes** | **No** | **N/A** | **Comments** |
| Investigational product received and stored in a suitable place |  |  |  |  |
| All study supplies for the study have been received |  |  |  |  |
| Facilities and equipment required are available and functional |  |  |  |  |
|  | | | | |
| **Date:** | **Completed By:** | | | |

**Site Activation Checklist**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | **Yes** | **Date** | **Comments** |
| IRB Approval Received for Protocol, Consent Form, and Other Applicable Documents | |  |  |  |
| Safety/Monitoring Committee (e.g., Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) review complete or confirmation that no Safety/Monitoring Committee will be required | |  |  |  |
| Site Essential Document File Approved | |  |  |  |
| Case Report Forms Final | |  |  |  |
| Data Management System Ready for Data Entry and Clinical Data Management Plan Drafted | |  |  |  |
| Study Materials on Site  *List types of required materials separately (e.g., specimen labels and tubes, questionnaires, supplies for procedures).* | |  |  |  |
| #1 |  |  |  |  |
| #2 |  |  |  |  |
| #3 |  |  |  |  |
| #4 |  |  |  |  |
| #5 |  |  |  |  |
| Site Initiation Visit Completed | |  |  |  |
|  | Trained on protocol, study procedures (MOP), electronic systems. (Note this requirement includes re-training, if site activation is more than 8 weeks after the site initiation visit.) |  |  |  |
|  | Facilities deemed acceptable |  |  |  |
| Action Items from Site Initiation Visit Required for Site Activation Completed | |  |  |  |
| Study Specific Requirements Met  *Update with relevant list* | |  |  |  |
| #1 |  |  |  |  |
| #2 |  |  |  |  |
| #3 |  |  |  |  |
| #4 |  |  |  |  |
| Schedule Study Activation Meeting with the UMMC Office of Clinical Trials  *(coordinate with your assigned OCT project managers)* | |  |  |  |
| **Date:** | | **Completed By:** | | |