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| **IRB Number:** | |  | | | **Sponsor:** |  |  |  |  |
|  | |  | | |  |  |  |  |  |
| **Protocol Number:** | |  | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |
| **PI:** |  |  |  |  | **Primary Coordinator:** |  |  |  |  |
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| **Completed** | **Task** | **Date Completed** | **Comments** |
| --- | --- | --- | --- |
|  | Feasibility Assessment (keep in mind the following):   * Adequate facility(ies) * Equipment * Staff * Patient Population * Budget |  |  |
|  | Schedule Site Qualification Visit (be prepared to tour facility(ies) where study will be conducted):   * Clinic/CTRC * Lab(s) * Pharmacy * Work areas for research staff * Monitor Space * Storage area for supplies |  |  |
|  | Submit IND/IDE application to FDA if applicable |  |  |
|  | Initiate Study into CRMS |  |  |
|  | Complete Billing Coverage Analysis and Submit   * Protocol * Sponsor’s Draft Consent |  |  |
|  | Submit Clinical Trial Agreement/Study Order to OCT |  |  |
|  | If applicable, obtain fees and codes from Integrated Billing |  |  |
|  | Complete and submit Investigational Drug Services request form (CRMS) |  |  |
|  | Negotiate and Finalize Budget with Sponsor |  |  |
|  | Submit Finalized Budget/Internal Budget to OCT |  |  |
|  | Submit eIPF in RAMSeS |  |  |
|  | Initiate and Submit IRB application |  |  |

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| **Completed** | **Task** | **Date Completed** | **Comments** |
|  | Complete Regulatory Packet and return to sponsor |  |  |
|  | If Device Trial for which subject will be billed, complete and submit required information to Palmetto GBA (can take awhile to receive approval) – contact UNC Healthcare Gov’t Program Analyst/Reimbursement for assistance |  |  |
|  | Ensure Billing Grid in Epic is correct |  |  |
|  | Contact IDS to request pharmacist assignment |  |  |
|  | Contract/Study Order Executed |  |  |
|  | Enter Required Study Information into Epic |  |  |
|  | Drug/Device delivered |  |  |
|  | Training completed:   * Study Staff * Ancillary Staff |  |  |
|  | Post on ClinicalTrials.gov if applicable |  |  |
|  | Develop study specific worksheets/source docs |  |  |
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