|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Pre-Study Task** | **PI** | **Study Coordinator** | **Regulatory**  **Coordinator** | ***<<Add Role>>*** | ***<<Add Role>>*** | **NOTES** |
| [**Submit Confidentiality Disclosure Agreement (CDA) to Office of Sponsored Programs (OSP**](https://www.uab.edu/research/home/osp-industry-projects/ind-other/confidentiality-disclosure-agreements)**)** |  |  |  |  |  |  |
| **Complete** [**UAB Protocol Feasibility Assessment Form**](https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk)  *(See* [*Clinical Trials Kiosk*](https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk) *– Investigator Toolkit or use site’s own feasibility assessment form)* |  |  |  |  |  |  |
| **Complete** [**UAB Recruitment and Retention Plan Worksheet**](https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk)  *(See* [*Clinical Trials Kiosk*](https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk) *– Investigator Toolkit)* |  |  |  |  |  |  |
| [**IRAP Project Registration/Single Identifier**](https://www.uab.edu/research/home/irap-training/project-registration) |  |  |  |  |  |  |
| [**OCS-CCTS-CBR Submission**](https://redcap.dom.uab.edu/surveys/?s=ELDN9LW9YP) *(if yes to any questions below)*   * Will the study involve [UAB Health System clinical billable services](https://www.uab.edu/medicine/ctao/investigators/clinical-billing-review/processes-forms)? * Is study be managed in [OnCore](https://www.uab.edu/ccts/clinical-research/oncore)? * Will study use [CCTS Clinical Services](https://www.uab.edu/ccts/clinical-research/clinical-services)? |  |  |  |  |  |  |
| **Develop and Negotiate budget**  *(See* [*Clinical Trials Kiosk*](https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk) *– Clinical Trials Budget Tools and Workshop)* |  |  |  |  |  |  |
| **Pre-Study** | **PI** | **Study coordinator** | **Regulatory** | **Manager/Administrator** | **Pharmacy** | **NOTES** |
| [**Submit Clinical Trial Agreement (CTA) & other required documents to OSP**](https://www.uab.edu/research/home/osp-researchers-toolkit/forms/required-documents) |  |  |  |  |  |  |
| **Regulatory**  *(See* [*Clinical Trials Kiosk*](https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk) *– Regulatory Coordinator Toolkit)*   * Complete Site Contact Sheet * Receive start-up packet from Sponsor/CRO (typically includes protocol, PSP, ICF, logs, recruitment materials, *some* essential documents, etc.) * Start and maintain ISF * Collect and maintain essential documents * IRB submissions |  |  |  |  |  |  |
| **Create Study Contacts and Vendors List**  *(See* [*Clinical Trials Kiosk*](https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk) *– All Tools and Templates)*   * Study Staff * Ancillary Staff * Vendors   + Lab, EDC, IWRS   + Electronic devices   + ECG, Radiology, etc. transmission   + Safety Reports   + Home/telehealth services   + Other |  |  |  |  |  |  |
| **Pre-Study** | **PI** | **Study coordinator** | **Regulatory** | **Manager/Administrator** | **Pharmacy** | **NOTES** |
| **Map out plans**   * Space * Logistics * Special considerations |  |  |  |  |  |  |
| [**Validate OnCore Calendar**](https://www.uab.edu/ccts/clinical-research/oncore/calendar-services) |  |  |  |  |  |  |
| **[Submit PowerTrials Study Summary](https://www.uab.edu/ccts/clinical-research/oncore/powertrials)** |  |  |  |  |  |  |
| [**Validate PowerPlan**](https://www.uab.edu/ccts/clinical-research/oncore/powertrials) |  |  |  |  |  |  |
| [**Greenphire set-up and obtain UAB ClinCards**](https://www.uab.edu/medicine/ctao/investigators/greenphire/documentation) |  |  |  |  |  |  |
| **Enter budget in Oncore**  *(Required for Industry Trials March 1, 2024. See* [*Clinical Trials Kiosk*](https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk) *– Oncore Financials)* |  |  |  |  |  |  |
| **Supplies & equipment**   * Make list * Place orders, if needed * Perform inventory checks throughout startup period |  |  |  |  |  | Remember, lab supplies may expire while waiting on study to open |
| **Create source docs**  *(See* [*Clinical Trials Kiosk*](https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk) *– Study Coordinator Toolkit)* |  |  |  |  |  |  |
| **Make subject binders** |  |  |  |  |  |  |
| **Complete required trainings** |  |  |  |  |  | Training logs filed in ISF. |
| **Pre-Study** | **PI** | **Study coordinator** | **Regulatory** | **Manager/Administrator** | **Pharmacy** | **NOTES** |
| **Recruitment**   * Distribute recruitment materials * Create recruitment log *(See* [*Clinical Trials Kiosk*](https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk) *– Study Coordinator Toolkit)* |  |  |  |  |  | Recruitment materials must have IRB approval. |
| **Schedule SIV** |  |  |  |  |  |  |
| **Attend SIV** |  |  |  |  |  |  |
| **Schedule internal study initiation meeting** |  |  |  |  |  | Have a team meeting prior to scheduling first screen to ensure everyone on the same page. (Or include as part of staff meeting) |
| **Engage clinic staff (MD, physician extenders, nurses)**   * Provide eligibility criteria * Keep ongoing list of potential participants |  |  |  |  |  |  |
| **Conduct mock visit** |  |  |  |  |  |  |