**Study Startup Checklist**

Texas Christian University

QA Program

|  |  |
| --- | --- |
| **Study Title** |  |
| **IRB Number** |  |
| **Principal Investigator** |  |
| **IRB Review Type** |  |
| **IRB of Record (Review or relying)** |  |
| **Funding** |  |
| **Department** |  |
| **Initial Approval Date** |  |
| **Study Risk Level** |  |
| **Current Enrollment** |  |
| **Target Enrollment** |  |
| **Review Date** |  |
| **Vulnerable Populations** |  |
| **QA Reviewer** |  |
| **Study Team Member Attending** |  |
| **Sponsor**  |  |
| **IND/IDE #** |  |

|  |  |
| --- | --- |
| Discussed | 1. Recruitment and Screening
 |
| Yes | **No** |  |
|  |  | Recruitment Methods: How will you recruit participants to study? (Does explanation match IRB application and approved protocol?) |
|  |  | Recruitment Materials: Has the IRB approved all recruitment / advertising materials? |
|  |  | Screening Procedures: Can you explain the screening procedures used in the study? (Does explanation match IRB application and approved protocol?) |
|  |  | Reminder: Ensure privacy in recruitment and screening procedures. |
|  |  | GCP / Best Practices |
|  |  | Procedures and forms to track and record recruitment (i.e if the protocol states interested participants may be contacted up to 3x, a log should be kept to document attempts.) |
|  |  | Procedures and forms to track and record screening procedures (i.e visit checklists) |
|  |  | Procedures and forms that consider data confidentiality |
| Comments and Follow-up Items: |

|  |  |
| --- | --- |
| Discussed | 1. Eligibility and Enrollment
 |
| Yes | **No** |  |
|  |  | Eligibility Determination: Can you describe the process you used to determine eligibility? (Does explanation match IRB application and approved protocol?) |
|  |  | Reminder: Study team members should be qualified through background and training to assist in determining eligibility? |
|  |  | Randomization (if applicable): How are subjects randomized? Ensure randomization is documented. |
|  |  | GCP / Best Practices |
|  |  | Document eligibility criteria using an eligibility checklist and file source documents for each criterion in the subject’s file. |
|  |  | Eligibility should be confirmed, signed, and dated by a qualified study team member prior to implementing study procedures. |
|  |  | Forms to track enrollment (i.e screening an enrollment log). |
|  |  | Forms to track withdrawals and reasons for withdrawals. |
| Comments and Follow-up Items: |

|  |  |
| --- | --- |
| Discussed | 1. Informed Consent
 |
| Yes | **No** |  |
|  |  | Informed Consent Process: How will you consent subjects to the study? The consent process should be conducted only be an IRB-approved member of the study team. Study team members should be qualified through background and training to assist in the informed consent process. |
|  |  | Reminder: Privacy of subjects is respected during the informed consent process |
|  |  | GCP / Best Practices |
|  |  | Download the consent document from the IRB application on the same day the participant is to be consented. This helps ensure the current version of the consent form is used. |
|  |  | Consent form should be signed prior to any study-specific procedures. |
|  |  | Give potential subject adequate time to ask questions and decide about participations. |
|  |  | Ensure that all spaces / elements of the document are appropriately completed (such as the signature, date, future use, and optional sub-study). Review this while the subject is still available in case errors can be corrected prior to implementing the study procedures. |
|  |  | Copy of consent is given to the subject (unsigned or signed is acceptable, depending on study). |
|  |  | Consent documents should be stored per the IRB-approved application (i.e separate from coded research data). |
|  |  | If consent document includes opt in/ opt out section(s), recommended a tracking system. |
|  |  | Method to track informed consent and re-consent process (if re-consent is required, it should be done at the next scheduled visit). |
|  |  | Consent process documented in clinical progress notes or source documents. |
| Comments and Follow-up Items: |

|  |  |
| --- | --- |
| Discussed | 1. Protocol Interaction / Intervention Adherence
 |
| Yes | **No** |  |
|  |  | Amendments: Ensure timely IRB submission of prospective protocol updates (get IRB approval prior to implanting changes unless the change is to avoid an immediate hazard to subjects). |
|  |  | Study Procedures: How do you plan to document study procedures? Ensure documentation is present for all study procedures as described in the IRB-approved protocol. |
|  |  | Protocol Deviation (PDs): PDs included both purposeful and accidental variance in the procedures outlined in the IRB-approved protocol or application (i.e missed visits or procedures and out-of-window visits). Report protocol deviations to the IRB per its reporting guidance. |
|  |  | GCP / Best Practices |
|  |  | Keep case history research records. |
|  |  | Develop a process to identify, trac, and manage abnormal laboratory results or diagnostic tests. |
|  |  | Keep documentations of protocol adherence. |
| Comments and Follow-up Items: |

|  |  |
| --- | --- |
| Discussed | 1. Protocol Interaction / Intervention Adherence
 |
| Yes | **No** |  |
|  |  | DSMB / DSMP: Ensure documentations of DSMB / DSMP oversight (DSMB monitoring reports should be submitted to IRB). |
|  |  | Risk / Benefit: Report changes in risk / benefit to IRB. |
|  |  | Adverse Event Reporting: Are you familiar with the IRB reporting guidelines? |
|  |  | Unanticipated Problems: Identify and report unanticipated problems to IRB. |
|  |  | GCP / Best Practices |
|  |  | Processes and forms to identify, track, manage, and report adverse events. |
|  |  | Follow-up with monitoring report observations as soon as possible. Keep documentation that corrections were made. |
|  |  | Process to track and follow-up on laboratory values out of normal range |
| Comments and Follow-up Items: |

|  |  |
| --- | --- |
| Discussed | 1. Study Documentation, Record Organization, and Confidentiality Protection
 |
| Yes | **No** |  |
|  |  | Confidentiality: Confidentiality protections consistent with IRB-approved submissions (is data (de-idenfied). Give recommendations based on IRB approval. |
|  |  | Encrypted Devices: Are you using encrypted devices to store study information?  |
|  |  | Records: What is your method for maintaining organized study record (paper or electronic)? Research documents should be organized, complete, up-to-date, and available. Subject records are readily accessible.  |
|  |  | Data: Data recorded on case report forms should be consistent with the source documents. |
|  |  | Logs: Study logs will vary depending on type of study (i.e screening and enrollment logs, adverse event logs, protocol deviation logs, specimen logs, drug/ device accountability logs, and monitoring logs). |
|  |  | GCP / Best Practices |
|  |  | All study forms are attributable (i.e signed and dated) |
|  |  | Data corrections are made appropriately (single line through error, date of correction, and initials of person(s) making correction) |
|  |  | “Notes to file” to correct minor issues in research records |
|  |  | Training log |
|  |  | Recruitment / screening log |
|  |  | Delegation / signature log |
|  |  | Protocol deviation log |
|  |  | Informed consent and re-consent log |
| Comments and Follow-up Items: |

|  |  |
| --- | --- |
| Discussed | 1. Study Oversight
 |
| Yes | **No** |  |
|  |  | Delegation: Delegate study activities only to qualified investigators and study team members. Recommended a delegation log. |
|  |  | Training: Do you document protocol training? Co-investigators and study steam members should be trained on the protocol and their study responsibilities |
|  |  | Supervision: Adequate and personal supervision of the conduct of an ongoing clinical trial |
|  |  | Conflicts of Interest: Ensure team is aware of conflict-of-interest management plan. Follow the plan (i.e individuals with conflicts of interest cannot consent). |
|  |  | GCP / Best Practices |
|  |  | Plans for communication between investigator and study team members and among study team members. |
|  |  | Documentation of PI oversight. |
| Comments and Follow-up Items: |

|  |  |
| --- | --- |
| Discussed | 1. Regulatory Responsibilities
 |
| Yes | **No** |  |
|  |  | IRB Submissions: Timely IRB submission for approval of protocol and consent form modifications. Timely response to requests from the IRB. |
|  |  | Hold/Suspensions: Voluntary holds / study suspensions by PI and IRB. |
|  |  | Scheduled Continuing Review: Continuing IRB obtained, as applicable. |
|  |  | Sponsor Communications: Keep all sponsor communications and submissions. |
|  |  | ClincialTrials.gov: If the study is an applicable clinical trial, is it listed on ClinicalTrials.gov? If yes, is it required wording in the informed consent form? Register within 21 days of first subject enrollment for all Phase II through IV trials of FDA-regulated drugs, biologics, and devices whether FDA-approved or no. Some journals require registration prior to enrolling the first subject as part of their publishing requirements.  |
|  |  | GCP / Best Practices |
|  |  | Terminated a study (do not let it lapse). |
| Comments and Follow-up Items: |

|  |  |
| --- | --- |
| Discussed | 1. Drug, biologic, or device accountability and handling for FDA-Regulated Studies
 |
| Yes | **No** |  |
|  |  | Accountability: Records of receipt, disposition and return. Documentation of transfer (i.e chain of custody). |
|  |  | Storage: Stored per protocol? Secure? If temperature control is required, is there a way to monitor it? Document any excursion. |
|  |  | Destruction: Expired? Leftover returns from subjects? Ensure any destruction is properly documented. |
|  |  | Labeling: Is the test article labeled for investigation use? For blinded trials, are the labels identical to protect the blind? |
|  |  | Blinded Trials: Is there an unblinding procedure in place in case it is needed? Ensure any unblinding are well documented. |
| Comments and Follow-up Items: |

|  |  |
| --- | --- |
| Discussed | 1. FDA Regulatory Responsibilities / Essential Documents of Investigator File
 |
| Yes | **No** |  |
|  |  | Regulatory documents organized, complete, available. |
|  |  | FDA 1572 (drug studies) or investigator agreement (device studies) current, signed, dated, complete, and correct. |
|  |  | Require curricula vitae on file |
|  |  | Financial disclosure forms completed by each listed investigator or Co-I involved in subject interactions and evaluations |
|  |  | Protocol and accompanying manuals or procedures (if any) available and current. |
|  |  | Clinical laboratory certifications (CAP or CLIA) and normal ranges present. |
|  |  | Clinical protocol amendments on file – respective modifications submitted for IRB review/ approval and FDA review, if applicable. |
|  |  | Keep all FDA communications and submissions |
| Comments and Follow-up Items: |