# Site preparation for a monitoring visit – Essential Documents

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol Number/Abbreviated Title: |  | Date of Review: |  |
| Study Coordinator/Delegate |  | Principal Investigator  |  |

| Document | Criteria | YES✓ | NO✓ | N/A✓ | Comments |
| --- | --- | --- | --- | --- | --- |
| Sponsor/Site contact List  | Ensure an updated contact list is filed in the Investigator Site File (ISF)  |  |  |  |  |
| HREC Approvals  | HREC Approval documentation is filed in chronological order in the appropriate section of the ISF. This can include **but is not limited to**;* Initial HREC submission/Approval
* Protocol amendment submission/approval
* Annual and safety reports
 |  |  |  |  |
| Approving HREC Committee | A HREC Membership composition is on file and has been updated annually. |  |  |  |  |
| TGA Notification (if required)  | (CTN/CTX) receipt is filed and the approved site is named on the receipt e.g. Bankstown Hospital  |  |  |  |  |
| Research Governance Approvals | RGO Acknowledgement/Approval documentation is filed in chronological order in the appropriate section of the ISF. This can include but is not limited to the initial Site Specific Application, protocol amendments and acknowledgement of Annual and safety reports |  |  |  |  |
| Clinical Trial Research Agreement (CTRA)  | Fully Executed CTRA for the site has been filed in the appropriate section of the ISF |  |  |  |  |
| Indemnity (if required)  | Fully Executed Indemnity for the site has been filed in the appropriate section of the ISF |  |  |  |  |
| Insurance (if required) | Current Insurance certificate has been filed in the appropriate section of the ISF |  |  |  |  |
| Protocol | A current and HREC approved copy of the Protocol is filed in the correct section of the Investigator Site File (ISF)  |  |  |  |  |
| ProtocolParticipant Information Consent Form (PICF)  | All previous/superseded versions of the Protocol are filed in the appropriate section of the ISF  |  |  |  |  |
| Signed versions of the protocol signature page are available for each version of the Protocol and filed in the appropriate section of the ISF   |  |  |  |  |
| A current and HREC approved copy of the PICF is filed in the correct section of the ISF |  |  |  |  |
| Participant Information Consent Form (PICF) Investigator Brochure (IB)  | All previous/superseded versions of the PICF are filed in the appropriate section of the ISF  |  |  |  |  |
| All signed PICFs are appropriately located in the ISF or participant file  |  |  |  |  |
| All approved and superseded IB’s are appropriately located in the ISF or participant file |  |  |  |  |
| FDA 1572 Forms & Supplements (as applicable) and Financial Disclosure Documents and Confidentiality agreements or equivalent  | Financial disclosure forms for all key personnel are present, signed and dated (if applicable). |  |  |  |  |
| Trial related Correspondence | Documentation of Trial specific Sponsor and internal correspondence is present and current. This can include emails, and documentation of phone conversations |  |  |  |  |
| Sponsor Newsletters |  |  |  |  |
| Monitoring Visit Logs (signed and dated)  |  |  |  |  |
| Follow up Letters |  |  |  |  |
| Internal Meetings/agenda and minutes (Trial Specific)  |  |  |  |  |
| Delegation Log | The Delegation of Responsibilities Log is present and current for all individuals accredited to perform specific study tasks **Please Note:** The PI must date delegation prior to individuals undertaking trial-related activity |  |  |  |  |
| Training Log  | Documentation of study-specific training for all relevant personnel is present and complete. **This includes any subsequent protocol amendment training**  |  |  |  |  |
| Screening and Enrolment Log  | The Site Screening and Enrollment Log is present and up-to-date. |  |  |  |  |
| Additional Training Documentation  | Curriculum Vitae (CV) for all trial staff is filed either in the trial ISF or located centrally. All staff require their CV to be updated every 2 years and include location of practice e.g. Liverpool Hospital |  |  |  |  |
| All clinical trial staff are required to have a GCP certificate. Filed either in the trial ISF or located centrally. All staff require their GCP to be updated every 3 years |  |  |  |  |
| Documentation of IATA training is present for individuals shipping specimens. |  |  |  |  |
| Documentation of EDC training e.g. Rave, Inform  |  |  |  |  |
| Study specific Manuals/Training material  | CRF completion manual/guide  |  |  |  |  |
| Training Material provided by the Sponsor/CRO e.g. SIV presentation slides  |  |  |  |  |
| Current Lab Manual  |  |  |  |  |
| Calibration of equipment  | Calibration Documentation (if appropriate) is available via the Biomedical Department. The SWSLHD Biomedical Department maintains all hospital based equipment using AFM Online; [https://www.ehealth.nsw.gov.au/programs/corporate/afm](https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ehealth.nsw.gov.au%2Fprograms%2Fcorporate%2Fafm&data=02%7C01%7CKate.Pascall%40quintiles.com%7C88a9c2d7e39645a4213f08d817fca51e%7C5989ece0f90e40bf9c791a7beccdb861%7C1%7C0%7C637285721187619656&sdata=Tnnu7vymEAEEDDEQTmtdvwmongS9vxV57szL7PlHX%2Fg%3D&reserved=0) |  |  |  |  |
| Pharmacy File oversight and management  | Investigational Product Accountability Records are present, accurate, and current.  |  |  |  |  |
| Shipping records for Investigational Product documenting the receipt date, quantity, and lot numbers are present and current. |  |  |  |  |
| Randomization list and decoding procedures for Blinded Investigational Product are present. |  |  |  |  |
| Investigational Product Temperature Logs are present, or their location is specified and easily accessible. |  |  |  |  |
| Refer to the SOP\_CTSU\_15 Managing the Investigational Product for further information and guidance  |  |  |  |  |
| Pathology Lab DocumentationSpecimen Tracking Logs | Laboratory certifications and accreditations are present and current  |  |  |  |  |
| Current Reference ranges are filled. These are required to be updated on a yearly basis |  |  |  |  |
| Specimen Tracking Logs or Retention Records are filed in the ISF, or in the participant file for reference  |  |  |  |  |
| Serious Adverse Events (SAE) and all other Safety Reports | Ensure that all participant safety events are recorded and reported as per the trial protocol and the NHMRC Safety requirements. Further guidance is provided in SOP\_CTSU\_19 Safety management and assessment  |  |  |  |  |
| Serious Adverse Events (SAE) and all other Safety ReportsNon-compliance documentation  | All Protocol non-compliance events are recorded and reported as per SOP\_CTSU\_20 Non-Compliance |  |  |  |  |
| Finance and Budget Documentation  | All invoice requests and reconciliation documentation All Budget documentation relating to the Trial  |  |  |  |  |
| Essential Documentation Storage  | All Essential documents are stored in accordance with ICH GCP (E6R2) Please refer to FM\_12\_Essential Document Storage Log for essential documentation/filing of this process.  |  |  |  |  |
| Other  |  |  |  |  |  |