# Site Participant Monitoring checklist

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol Number/Abbreviated Title: |  | Date of Review: | <Specify date review completed or date range, if multiple days> |
| Study Coordinator or delegate  |  | Principal Investigator  |  |

| Item | Criteria for all enrolled participants  | YES✓ | NO✓ | N/A✓ | Comments |
| --- | --- | --- | --- | --- | --- |
| Informed Consent Process and Documentation | Current, approved version(s) of the PICF has been signed and dated in by the PI/Delegate and participant. If required appropriate impartial witness in line with ICH-GCP requirements |   |   |   |   |
| Documentation in the participant medical record process including that the participant was provided a full explanation of the study, and adequate time was given for consideration and questions regarding study participation. A copy of the signed consent form is provided to the participant/person responsible. The original is filed in the ISF or Participant file.  |   |   |   |   |
| The participant and/or legally authorized person responsible signed and dated the Consent Document prior to initiation of study-specific procedures. |   |   |   |   |
| Eligibility Criteria | The participant has met all Inclusion Criteria and none of the Exclusion Criteria for the study. This is clearly documented in the participant medical notes during the initial consent conversation with the PI/Delegate |     |     |     |     |
| Concomitant Medications | A Concomitant Medications is consistent and complete between Source Documentation and Case Report Forms (CRF/eCRF). |    |    |    |    |
| Investigational Product Management Processes | Investigational product and/or Device has been stored, dispensed and administered per protocol and documented in line with SOP\_CTSU\_15 Managing Investigational Product and SOP\_CTSU\_16 Managing Investigational Device  |   |   |   |   |
| Adverse Event (AE), and/or Serious Adverse Event (SAE) Identification and Reporting | AEs, and SAEs have been identified, recorded, and reported properly and within the specified timelines in line with the approved protocol and contractual agreement |   |   |   |   |
| Missed Visits and Follow-up | Has the participant has missed one or more study visits. |   |   |   |   |
| If yes, missed visits are documented according to protocol and institutional requirements. Documentation of attempts to contact the participant is present (i.e., phone call, certified mail, etc.). If missed visits resulted in a protocol deviation, they have been recorded as protocol non-compliance. Refer to SOP\_CTSU\_20 Non-Compliance  |   |   |   |   |
| Missed Lab Tests/Procedures | All protocol-required lab tests and procedures have been performed and signed/dated by the PI or deleagte |   |   |   |   |
| If no, missed tests/procedures have been reported as protocol non-compliance. Refer to SOP\_CTSU\_20 Non-Compliance |   |   |   |   |
| Study Discontinuation | If the participant has discontinued study product or study visits, all protocol-required steps have been followed. |   |   |   |   |
| Participant has been provided standard of care treatment as applicable  |  |  |  |  |
| Source Documentation | Source Documentation Standards are being followed in accordance with ICH-GCP |   |   |   |   |
| All entries are signed and dated. |   |   |   |   |
|  |   |   |   |   |
| Signatures of personnel signing are present in the Delegation Log  |   |   |   |   |
| Error corrections are properly executed in accordance with ICH-GCP  |   |   |   |   |