|  |
| --- |
| **ESSENTIAL DOCUMENT CHECKLIST** |
| **Prior to Clinical Trial Implementation** |
| **Title of Document**  | **Purpose**  | **Located in Files of Investigator/ Institution**  | **Located in Files of Sponsor** |
| Investigator’s Brochure  | To document that relevant and current scientific information about the investigational product has been provided to the investigator. | X  | X  |
| Signed protocol and amendments, if any, and sample case report forms (CRFs)  | To document investigator and sponsor agreement to the protocol/amendment(s) and CRFs. | X (copy)  | X (original) |
| Information given to trial subject - Informed consent form (Including all applicable translations)  | To document the informed consent. | X  | X  |
| Advertisement for subject recruitment (if used) | To document that recruitment measures are appropriate and not coercive. | X  |   |
| Financial aspects of the trial  | To document the financial agreement between the investigator/institution and the sponsor for the trial. | X  | X  |
| Insurance statement (where required)  | To document that compensation to subject(s) for trial-related injury will be available. | X  | X  |
| **Title of Document** | **Purpose** | **Located in Files of Investigator/ Institution**  | **Located in Files of Sponsor** |
| Signed agreements between involved parties, such as: * Investigator/institution and sponsor
* Investigator/institution and CRO
* Sponsor and CRO
* Investigator/institution and authorities (where required)
 | To document agreements.  |  X |  X (where required)  |
| Dated, documented IRB approval of the following: * Protocol and any amendments
* CRFs (if applicable)
* Informed consent form(s)
* Any other written information to be provided to the subject(s)
* Advertisement for subject recruitment (if used)
* Subject compensation (if any)
* Any other documents given approval
 | To document that the trial has been subject to IRB review and given the version number and date of the approval. To identify document(s).  |  X  |  X  |
| Institutional review board/independent ethics committee composition  | To document that the IRB is constituted in agreement with GCP. |  X  |  X (where required)  |
| Regulatory authorities authorization/approval/notification of protocol (where required)  | To document appropriate authorization/approval/notification by the regulatory authority(ies) has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s). |  X (where required)  |  X (where required)  |
| **Title of Document** | **Purpose** | **Located in Files of Investigator/ Institution** | **Located in Files of Sponsor** |
| Curriculum Vitae (CV) and/or other relevant documents evidencing qualifications of investigator(s),sub-investigator(s) and other study personnel, if applicable. | To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects. |  X  |  X  |
| Normal value(s)/range(s) for medical/laboratory/technical procedure(s) and/or test(s) included in the protocol  | To document normal values and/or ranges of the tests. |  X  |  X  |
| Medical/laboratory/technical procedures/tests and Certification or Accreditation or Established quality control and/or external quality assessment or Other validation (where required)  | To document competence of facility to perform required test(s), and support reliability of results. |  X (where required)  |  X  |
| Sample of label(s) attached to investigational product container(s)  | To document compliance with applicable labeling regulations and appropriateness of instructions provided to the subjects. |   |  X  |
| Instructions for handling of investigational product(s) and trial-related materials (if not included in protocol or investigator’s brochure)  | To document instructions needed to ensure proper storage, packaging, dispensing, and disposition of investigational products and trial-related materials. |  X  |  X  |
| Shipping records for investigational product(s) and trial-related materials | To document shipment dates, batch numbers, and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability.  |  X  |  X  |
| **Title of Document** | **Purpose** | **Located in Files of Investigator/ Institution** | **Located in Files of Sponsor** |
| Certificate(s) of analysis of investigational product(s) shipped | To document identity, purity, and strength of investigational products to be used in the trial. |  | X |
| Decoding procedures for blinded trials  | To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subjects’ treatment. |  X  |  X (third party if applicable)  |
| Master randomization list  | To document method for randomization of trial population. |   |  X (third party if applicable)  |
| Site Selection Notification  | To document that the site is suitable for the trial. |   |  X  |
| Trial initiation monitoring report  | To document that trial-related procedures were reviewed with the investigator and investigator’s trial staff. |  X  |  X  |
| **During the Conduct of the Trial** |
| Investigator’s Brochure updates  | To document that investigator is informed in a timely manner of relevant information. |  X  |  X  |
| Any revisions to: * Protocol
* CRFs
* Informed consent form(s)
* Any other written information provided to subjects
* Advertisement for subject recruitment (if used)
 | To document revisions of these trial- related documents that take effect during the conduct of the trial. |  X  |  X  |
| **Title of Document** | **Purpose** | **Located in Files of Investigator/ Institution** | **Located in Files of Sponsor** |
| Dated, documented approval by the Institutional Review Board (IRB) of the following revisions:* Protocol amendment(s)
* Informed consent form(s)
* Any other written information to be provided to the subject
* Advertisement for subject recruitment (if used)
* Any other documents given approval
* Continuing review of trial
 | To document that the amendment(s) and/or revision(s) have been subject to IRB review and were given approval. To identify document(s) version number and date of the revision and/or approval. |  X  |  X  |
| Regulatory authority(ies) authorizations/ approvals/notifications where required for protocol amendment(s) and other documents  | To document compliance with applicable regulatory requirements  |  X (where required)  |  X  |
| Curriculum Vitae (CV) for new investigator(s),sub-investigators, or other study personnel, if applicable.  | To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects. |  X  |  X  |
| Updates to normal value(s)/range(s) for medical laboratory/technical procedure(s)/test(s) included in the protocol  | To document normal values and ranges that are revised during the trial. |  X  |  X  |
| Updates of medical/laboratory/technical procedures/tests, Certification or Accreditation or Established quality control and/or external quality assessment or Other validation (where required)  | To document that tests remain adequate throughout the trial period. |  X  |  X  |
| **Title of Document** | **Purpose** | **Located in Files of Investigator/ Institution** | **Located in Files of Sponsor** |
| Documentation of investigational product(s) and trial-related materials  | To document all inventory, including detailed information regarding amounts, descriptions, shipping, receiving and return dates.  |  X  |  X  |
| Certificate(s) of analysis for new batches of investigational products (sponsor only) | To document identity, purity, and strength of investigational products to be used in the trial. |   |  X  |
|  Monitoring visit reports  | To document site visits by, and findings of, the clinical trial monitor. |   |  X  |
| Relevant communications other than site visits* Letters
* Meeting notes
* Documentation of telephone calls
 | To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting. |  X  |  X  |
| Signed informed consent forms and/or HIPAA authorization  | To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial.  |  X  |   |
| Source documents  | To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject. |  X  |   |
| **Title of Document** | **Purpose** | **Located in Files of Investigator/ Institution** | **Located in Files of Sponsor** |
| Signed, dated, and completed case report forms (CRFs)  | To document that the investigator or authorized member of the investigator’s staff confirms the observations recorded. |  X (copy)  |  X (original)  |
| Documentation of CRF corrections  | To document all changes/additions or corrections made to CRF after initial data were recorded. |  X (copy)  |  X (original)  |
| Notification by originating investigator to sponsor of serious adverse events and related reports  | Notification by originating investigator to sponsor of serious adverse events and related reports in accordance with 4.11 of ICH GCP. |  X  |  X  |
| Notification by sponsor and/or investigator, where applicable, to regulatory authority(ies) and IRB(s) of unexpected serious adverse drug reactions and of other safety information  | Notification by sponsor and/or investigator, where applicable, to regulatory authorities and IRB(s) of unexpected serious adverse drug reactions in accordance with ICH GCP 5.17 and 4.11.1 and of other safety information in accordance with 4.11.2 and 5.16.2. |  X (where required)  |  X  |
| Notification by sponsor to investigators of safety information  | Notification by sponsor to investigators of safety information in accordance with ICH GCP 5.16.2. |  X  |  X  |
| **Title of Document** | **Purpose** | **Located in Files of Investigator/ Institution** | **Located in Files of Sponsor** |
| Interim or annual reports to IRB and authority(ies)  | Interim or annual reports provided to IRB in accordance with ICH GCP 4.10 and to authority(ies) in accordance with 5.17.3. |  X  |  X (where required)  |
|  Subject screening log  | To document identification of subjects who entered pre-trial screening. |  X  |  X (where required)  |
|  Subject identification code list  | To document that investigator/institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any subject. |  X  |   |
|  Subject enrollment log  | To document chronological enrollment of subjects by trial number. |  X  |   |
| Investigational product(s) accountability at the site  | To document that investigational products(s) have been used according to the protocol. |  X  |  X  |
| Delegation of Authority log | To document signatures and initials of all persons authorized to make entries and/or corrections on CRFs. |  X  |  X  |
| Record of retained body fluids/tissue samples (if any)  | To document location and identification of retained samples if assays need to be repeated. |  X  |  X  |
| **Title of Document** | **Purpose** | **Located in Files of Investigator/ Institution** | **Located in Files of Sponsor** |
| **Termination of the Trial** |
| Investigational product(s) accountability at site  | To document that the investigational product(s) have been used according to the protocol. To document the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor. |  X (copy) |  X (original if requested by sponsor) |
| Documentation of investigational product(s) destruction  | To document destruction of unused investigational product(s) by sponsor or at site. |  X (if destroyed at site) (copy)  |  X (original if requested by sponsor) |
| Completed subject identification code list  | To permit identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time. |  X  |   |
| Audit certificate (if required)  | To document that audit was performed (if required) (see ICH GCP section 5.19.3). |   |  X  |
| Final trial close-out monitoring report  | To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files. |   |  X  |
| Treatment allocation and decoding documentation  | Returned to sponsor to document any decoding that may have occurred. |   |  X  |
| **Title of Document** | **Purpose** | **Located in Files of Investigator/ Institution** | **Located in Files of Sponsor** |
| Final report by investigator/institution to IRB where required, and where applicable, to the regulatory authority(ies) (see ICH GCP section 4.13)  | To document completion of the trial. |  X  |   |
| Clinical study report (see section 5.22)  | To document results and interpretation of trial. |  X (if applicable)  |  X  |