# Source Documentation Checklist

|  |  |
| --- | --- |
| Title of Study |  |
| Subject ID |  |

Source documentation for each subject enrolled in the study should include:

|  |  |
| --- | --- |
| [ ]  | Information about the date/time that the subject, or their legally authorized representative, received the Informed Consent document (ICD) for review. |
| [ ]  | Information about the date/time that the subject, or their legally authorized representative, signed and dated the ICD prior to any research procedures being performed. |
| [ ]  | Name of Principal Investigator and Protocol Number, Site Name and Number, Subject Initials, Subject Study Number, Date of Visit. |
| [ ]  | Original or copies of the results of all screening tests, evaluations or procedures used to determine subjects eligibility for the study. |
| [ ]  | Documentation that subject has met all of the inclusion criteria and none of the exclusion criteria and is eligible to enroll in the study. This must be signed and dated by PI or delegated staff. |
| [ ]  | Date of enrollment/randomization into the study, protocol number and subject number. |
| [ ]  | Record of any concomitant medications and medications discontinued (as specified by the protocol). |
| [ ]  | Record of subject’s diagnosis and status prior to treatment, including documentation of medical history, particularly that which is relevant for the disease or condition being treated. |
| [ ]  | Record of names of study drugs and dosing times, or other investigational product use. |
| [ ]  | Relevant dates and the results of evaluations and procedures required by the study; note any deviations from the protocol and provide an explanation. |
| [ ]  | Review and documentation of any Unanticipated Problems/Events, Adverse Events or SAEs that occurred during the treatment period and for a period specified by Sponsor/CRO following the last use of the investigational product; record any treatment administered and/or recommended. |
| [ ]  | Record subject’s condition during and/or after treatment. |
| [ ]  | Record of final disposition of the subject and subject status at time of study completion. |

Printed name of person that completed this checklist:

­­­­­­­­­­­­­­­­­­­­­­­­­­­­

Signature of person that completed this checklist: Date:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_