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**List of items to be included in study files**

This document clarifies the standard content of the subject source documentation checklist:

* It is the responsibility of the Principal Investigator (PI) to ensure compliance with Good Clinical Practice (GCP), Institutional Review Board (IRB), and other regulatory requirements.
* This document serves as a template and may be modified for study specific needs /requirements.
* Store items in a consistent chronological order, whether paper or electronic.
  + For paper subject source records, use a consistent chronological method.

**List of items to be included in a subject file**

* Informed Consent Form (ICF), signed original
* Health Insurance Portability and Accountability Act (HIPAA) form, signed original (if applicable)
* Informed Consent Process Documentation
* Eligibility Checklist (Inclusion/Exclusion Criteria) reviewed/signed/dated by the Principal Investigator (PI) prior to subject’s enrollment into the study.
* Eligibility Supporting Documents: any assessment (e.g., diagnostic test, lab results including the pregnancy test result for female subjects, operative procedure required to assess eligibility to enroll the subject into the study – all need to be reviewed/signed/dated by the PI
* Screening/Randomization/study visit verification from IVRS- Source documentation from the Sponsor
* All study visits documentation – all assessments need to be filed/ reviewed/signed/dated by the PI where required.
* Investigational Product (IP) – Labels of Device/Drug Dose administered to the subject
* Concomitant Medication Log- PI needs to sign/date at the completion of the study.
* Adverse Event (AE) and Serious Adverse Event (SAE): IRB submission and supporting documents- PI needs to review/sign/date in a timely fashion.
* End of Study Visit or Completion of the subject’s participation in the study signed and dated by the PI.
* Review of data collection tools/ procedures
* Lost to follow up – Documentation of the correspondence including the telephone calls between the site and Subject.
* Documentation of terms of subject termination from the study.
* Protocol deviations – need to be signed/dated by PI.
* Study visit Lab results - PI’s review for clinical significance/ signed/dated by the PI in a timely fashion.
* Subject end of study documentation (completion, screen fail, or withdrawal from the study – include reason)

**Note to File**

* Any missing documents, location of important documents not stored in the Master Regulatory File/Subject File should have a “Note to File”(NTF) filed in the appropriate section to explain the reason(s) for missing document(s) and/or the alternate location of the information.
* These may include site generated and /or sponsor generated notes to file. Sponsor generated NTF may be global or site specific.
* If documents are maintained electronically, write a NTF indicating the location and who maintains them (include copy of NTF here)
* If documentation is filed separately, write a signed/dated NTF indicating the location (include NTF here)
* A NTF should:

1. Be generated on a case-by-case basis.
2. Include the subject and protocol it refers to
3. Be signed/dated by the individual who is writing it
4. Be legible if handwritten
5. Explain clearly and specifically the reason for the error/omission/discrepancy or process /policy it aims to address
6. Should include any corrective action or follow –up when applicable.
7. Be filed with and/or behind the subject file tab to which it applies.