The Subject Binder

An investigator must prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation, the study intervention and the subject's response. The subject file is separate from the subject's medical chart and the study regulatory binder.Use the checklist below to organize subject records, as applicable to the trial.

1. Subject Information & Consent forms
    - Subject contact & emergency contact information
    - Signed consent forms / HIPAA Authorizations (initial, sub-study and any re-consent/authorizations)
    - Informed Consent note
2. Inclusion/Exclusion Criteria
    - Signed and dated checklist documenting that the subject met study entry criteria
    - Supportive documentation, as applicable:
        - Medical history provided by subject
        - Copies of pertinent sections of a medical record
        - Physical Exam
        - Results of Screening tests
3. Subject randomization Information
    - Note: If the study is double blind, no documentation should be included here that may inadvertently break the blind
4. Subject Notes (Divided by Visit)
    - Documentation of all observations/assessments relating to the subject(for example, physical exams, response to treatment and adverse event collection)
    - Documentation of all interventions described in the protocol (for example, details of inpatient study drug administration)
    - Results of all protocol required testing (for example, laboratory, imaging, EKG)
    - Documentation of all education and reinforcement provided to subject related to study procedures
    - Completed questionnaires, subject diaries, data collection forms etc.
5. Communication
    - Letters and emails to research subjects
    - Record of calls made to subjects, including a summary of information discussed. A telephone log is recommended.
6. Notes to file
    - Notes to file relating to a particular study document should be filed with that document. Ifthe note does not relate to a particular study document, it should be filed here.
7. Adverse Event Log
8. Protocol Deviation Log