# Gudiance: The Subject File

**Background**

An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual. The subject file is separate from the subject’s medical chart and the study administrative file (often called the regulatory binder for drug and device studies).

**Introduction**

When creating a subject file, it is most commonly done in the form of a ring binder notebook. Label the subject binder with the protocol number, participant initials and the participant’s study ID number. A subject binder must be kept for each subject in a given study. If a subject is permitted to be enrolled in more than one study, a new subject binder must be created and maintained for each study.

**Note**: plans to permit enrollment of subjects in more than one study simultaneously must be noted in the study protocol and reviewed and approved by the IRB.

**Elements of the Subject Binder:**

The subject binder should include the following sections and associated items. Create labeled tabbed section dividers for each section. The following lists the sections by number, followed by the items within that section:

1. Subject Information & Consent forms
   1. Subject contact & emergency contact information
   2. Signed consent forms / HIPAA Authorizations (initial, sub-study and any re-consent/authorizations)
      * **NOTE**: Copies may be kept in the subject’s folder if all original signed consent forms are filed together in a separate Subject Consent Master File
2. Inclusion/Exclusion Criteria
   1. Checklist for documenting the subject meeting inclusion exclusion criteria
   2. Supportive information used to confirm inclusion/exclusion as applicable, e.g.:
      * Recruitment forms
      * Screening tests
      * Copies of pertinent sections of a medial record
3. Visit notes

This section can contain sub-sections as applicable:

* 1. Visit notes: notations related to interactions with the subject, including not only physical examinations by the study team, but also treatment administration and accountability, protocol deviations, etc.
  2. Telephone log
  3. Questionnaires, diaries, etc.

1. Adverse Event and Unanticipated problem reporting

This section can either be a subsection of the visit notes, or its own section and is intended to capture the information used to report adverse events or unanticipated problems to the IRB or other entities (e.g. the study sponsor, federal sponsors or regulatory agencies, etc.)

1. Clinical tests

This section should contain sub-sections as appropriate to store the results of clinical testing supporting the research protocol, e.g.

* 1. Laboratory
  2. Cardiology
  3. Imaging

**Note**: Be sure to have PI or medically licensed designee sign off as “clinically significant” (CS) or “not clinically significant” (NCS)

1. Correspondence
   1. This section is for letters and emails to research subjects and their surrogates.
2. Notes to file
   1. This section relates to any notes to file used to explain protocol deviations or corrective actions
   2. Reports of non-allowable HIPAA disclosures
3. Medical Record information
   1. Use this section to store any copies made from the subject’s medical record.
4. Case report forms (CRFs)
   1. For paper-based CRFs:
      * Copies of completed Case Report Forms (CRF) **and** copies of data queries and responses
      * Corrections made on a CRF should be dated, initialed and if necessary explained. Draw a single line through the incorrect entry but do **not** erase or obscure the original entry. **Never** use correction fluid or throw out data that has been corrected
   2. For electronic data collection:
      * The software should have the capability of an audit trail: who entered the data, who changed the data, and date and times stamps for all such actions.
      * For changed data, the system must be able to retain the original data in the audit trail will displaying the current data on the form

**Configuring the Subject Binder**

The above is a suggested configuration, but it is important to configure the subject binder as appropriate to the specific study. Consider certain important items such as allergies or parts of the consent that the subject did not agree to sign, for example “the subject did not agree to donate biospecimens.” Sections can be organized by visit, type of documents or any other logical system.

The subject binder should contain **all** the information (source documentation) used to complete the case report forms (CRFs) as well as substantiating documentation for notes, I/E criteria and the quality of the informed consent process.

**Ongoing maintenance**

Updating the subject binder or file should be done on an **ongoing** basis so when the study is audited the subject binder is ready without any extra work or preparation. The subject binder should be designed to be self-explanatory which creates greater efficiency in managing a study, and also supports a smoother review by a study monitor or auditor.