CNS-B-01 — SUBJECT VISIT FILES AND ACCRUAL RECORDS

Background and Purpose

This SOP describes the procedures for setting up and maintaining subject visit files and accrual records. Subject visit files are maintained for purposes of documenting informed consent, for storing hard copy records of subject contact information and for recording all study-specific procedures carried out on subjects as they are enrolled into and proceed through studies. The information from subject visit files is used for assisting in scheduling study specific procedures and for maintaining electronic accrual records of all subjects considered and enrolled in a particular IEC or IRB approved study protocol. Subject visit files also contain the unique identifier used to maintain confidentiality of medical or research data and biological specimens collected in the course of study specific procedures. Therefore, subject visit files are **NOT** used for purposes of maintaining hard copies of medical records, study data or any research related personal information (e.g., case report forms) other than that maintained in visit plan records and required for maintaining communications with subjects and their relatives and personal physicians as designated by subjects at enrollment.

Visit Files

Subject visit files contain the original completed, signed and dated consent documents enabling participation of the subject into the study. The signature page is labeled with the unique identifier for the particular subject enrolled into the study.

Each subject visit file also contains a subject visit plan record. The subject visit plan record contains the complete contact information for each subject enrolled into the study together with contact information for a designated relative and personal physician if relevant or available. The subject visit plan record is also labeled with unique identifier for the subject. The visit plan record additionally includes fields required for directing study specific procedures and for recording the dates of study specific procedures according to the study protocol. Information for visit plan records may be collected onto hard copy forms or electronic forms, but in the latter case a hard copy form is also maintained in the subject visit file.

In studies requiring the use of unique identifiers sticky labels (e.g., for labeling blood tubes), those labels are also most appropriately stored in the visit file for that particular subject. Such sticky labels may also be used to label consent forms, subject visit plan records, case report forms and other files as appropriate with the unique identifier designated for that study subject.

Subject visit files accompany subjects as they progress though protocol stipulated procedures, but otherwise are stored in a secure location.

Accrual Records

Information from individual subject visit plan records is either hand transcribed (i.e., from hard copy forms) or electronically transmitted (i.e., from electronic forms) into an electronic spreadsheet or database record that contains the accrual data of all subjects enrolled into the study. Accrual records are updated regularly as subjects are recruited into the study.

Confidentiality

Excluding the medical records maintained for routine patient care, the subject visit files and electronic accrual records represent the only places where personal information identifying a study participant is maintained. All other research related information (e.g., case report forms, electronic data) is encoded according to the unique identifier assigned to the particular subject; the latter data are therefore stored and maintained separately from subject visit and electronic accrual records. When not in use, visit files are stored in a secured location. Access to electronic accrual records is password protected.