Subject Research Chart
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A research chart is recommended for each subject enrolled in, or screened for, a clinical research project. Research charts should be organized in a consistent manner so that research documentation is easily retrieved by any authorized individual that needs to access the information.

This tool was developed to assist investigators and research teams in organizing their subject documents. This tool is to be used as guidance; research teams are not required to follow the exact grouping or sequence of the document. It details which documents may be stored in each section of a study specific subject research chart. Some of the sections, or documents, are not applicable to all studies. In addition, some sponsors, CROs, or federal agencies may require that investigators keep additional documents that are not specifically referenced in this guidance.

Section	Contents
Label	Preferably on the front cover and spine of the binder there should be a label clearly indicating the subject's ID number, as well as the short-name for the study protocol.
Demographics/Face Sheet	Documentation to include pertinent subject information (e.g. name, birthdate, medical record number) including preferred contact information.
Study schematic/protocol calendar	Usually found within the protocol, this document outlines the list of required observations, assessments, and procedures for each study visit.
Correspondence	All relevant and pertinent study correspondence regarding or with the subject should be included (e.g. communication log to document subject interactions, copies of reminder letters, etc.).
Informed Consent	• Include copies of all consent/assent forms signed by the subject/parent throughout the study. Also ensure that the most current IRB approved version is provided to the patient at the next visit after the approval. Once approved and signed by all parties promptly place a copy in the subject binder. • Informed consent process documentation should include: subject number, protocol name the purpose, procedures, risks, benefits, and voluntariness has been explained to the subject, the subject was given adequate time to consider participation and ask questions and they agree to participate. • The informed consent process documentation should also include the time/date consent was obtained, that the subject was provided with a copy of the (signed) informed consent and study procedures were not performed prior to obtaining informed consent. • The same procedure(s) need to be followed if the subject is asked to reconsent to the study during their participation.
Inclusion/Exclusion Checklist	This document could be stored in the Screening Visit section of the subject chart and be referred to again prior to enrollment/ randomization or this checklist could be filed in its own section.
Subject Visit # (separate section for each visit)	Visit Checklist to serve as reminder of the procedures, order of procedures, and/or additional questions to be asked of the subjects during their visit(s).

Subject Visit # (separate section for each visit) *(continued from previous page)*	All pertinent source documentation related to that visit/encounter should be filed together in that visit section. Screening documentation to determine eligibility • Medical history and current medication(s) including applicable supporting inpatient/outpatient medical records • Other relevant results (i.e. laboratory, pathology, radiology reports) Ongoing study procedure documentation • Progress notes (a progress note should be written at each study visit that includes procedure performed, how the subject tolerated the procedures and any other relevant data) • Admission/Discharge forms • Clinical letters/ consultation letters • Pathology reports • Radiology reports • Surgical reports • Laboratory reports • Data Clarification forms • Scales/Questionnaires Subject diaries/calendars
End of Study/Early Withdrawal Form(s)	If your study uses a separate form to document the end of a subject's study participation, this form could be filed within a visit section or in its own section.
Deviation/Violation Form or Tracking Log	If your study uses a separate form to document each Deviation/Violation, it is recommended to have multiple copies of these forms available in each subject chart.
Adverse Event Tracking Log	Information elicited from the subject as to adverse events, or serious adverse events. This information must be documented with specific detail as to the date of first occurrence and when the event concluded. If the subject reports a hospitalization (SAE) the appropriate source documentation (i.e. health record, discharge summary) should be kept with the SAE report. This log should be reviewed and updated (if applicable) at each subject visit.
Serious Adverse Event (SAE) Form	If your study uses a separate form to document each Serious Adverse Event, it is recommended to have multiple copies of these forms available in each subject chart.
Concomitant Medication Log	Documentation to include all medications and supplements the subject is taking from the time consent is obtained through subject completion (including dose, route of administration, indication, and start/stop dates). This should be reviewed and updated (if applicable) at each subject visit.
Investigational Product Dispensation/Accountability *(if applicable)*	• Shipment transmittals • Product dispensation, return, and accountability log to document treatment compliance and final disposition

REMINDER: Subject Research Charts contain protected health information and should be stored in a secure area.