Study Tools and Templates

The study tools and templates provided are intended to help research teams:

1. **Document** required information
2. **Organize** study documents
3. **Track** study procedures

Before selecting a template, take the time to think about what data is required. Create a list of the information you need to document and track, and only then should you select a template to build from. **Do not let a template influence what data you will collect, but rather modify the template to collect the data you need.**

Once you have a template selected, customize the form to fit the specific needs of the study and research team. When tailoring the template, remember to:

- Use a legible font and font size
- Provide ample space to enter complete and legible data
- Design the form to be user-friendly -- easy to update, understand and maintain
- Consider where the form will be filed and how it will be updated (electronically or paper) - must be safe and secure, but accessible for updating and reference.

To use any of our study templates below, click on the template name to open the document in MS Word format. For more detailed description and ideas on how to use the template, click on the corresponding **Guidance** document (if available).

Research Staff and Training	
Roles & Responsibilities Log V1 ↳ Guidance for Roles & Responsibilities Log	Outlines each staff member's roles and responsibilities, including time on study and contact information.
Staff Training Log V1 **Staff Training Log** V2 ↳ Guidance for Staff Training Log	Lists all approved staff, documents their signature and the time frame each staff member was delegated specific tasks for the study.
Staff Signature Log ↳ Guidance for Staff Signature Log	Lists all approved staff, documents their signature and the time frame each staff member was delegated specific tasks for the study.
Clinical Trial Tasks	Outline of common study tasks involved in the execution of a study

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Study Tracking and Documentation

Subject Screening Log ↳ Guidance for Subject Screening Log	Tracks and documents all potential subjects screened.
Subject Enrollment Log ↳ Guidance for Subject Enrollment Log	Tracks and documents progress of enrolled subjects.
Subject Eligibility Checklist	Documents that approved inclusion/exclusion criteria is evaluated and verifies all inclusion criteria is met prior to enrolling the subject
Study Visit Checklist ↳ Guidance for Study Visit Checklist	Documents what study activities were completed at each visit.
Informed Consent Checklist	Checklist to ensure all required steps taken when obtaining consent; and to provide secondary documentation of the process.
Memo-to-File ↳ Guidance for Memo-to-File	Documents and explains any discrepancies in study data or processes.
Monitoring Log ↳ Guidance for Monitoring Log	Documents all reviews of the study from outside monitors (e.g. site visits, sponsor monitors, FDA audits, etc.).
Communication Log Template	Documents pertinent conversations regarding the study.
Recruitment Activity Log ↳ Guidance for Recruitment Activity Log	Tracks recruitment activities and used to evaluate which activities are most successful.
Remuneration Log **Remuneration Vouchers**	Tracks all remuneration obtained by study staff and distributed to research subjects
Deviation Log V1 **Deviation Log** V2	Documents and explains protocol deviations, and may be used to submit accumulated minor deviations to the IRB at the time of continuing review
Drug Accountability Log V1 **Drug Accountability Log** V2 ↳ Guidance for Drug Accountability Log	Documents and tracks investigational drug dispensation and accountability.
Device Accountability Log V1 **Device Accountability Log** V2	Documents and tracks investigational device and accountability.
IRB Tracking Log V1 **IRB Tracking Log** V2 ↳ Guidance for IRB Tracking Log	Tracks IRB submissions, actions, PI responses and other pertinent correspondence.
Consent Revision Log ↳ Guidance for Consent Revision Log	Documents and tracks revisions made to the consent and assent forms.
Clinical Trial Study Documents V1 **Clinical Trial Study Documents** V2	List of common study documents that the research team are responsible for maintaining throughout the research trial
Study Document Retention Inventory	Tracks study document storage, retention and destruction.
CRF-Source Document Log	Lists study Case Report Forms (CRF)/data points and the corresponding source documents that will be used to verify.

Study Tools and Templates

General Guidance and Information	
Subject Case History	Guidance on creating comprehensive and complete subject case histories.
Electronic Storage of Study Data and Documents	Provides guidance to ensure study data stored electronically meet the same fundamental elements of quality that are expected of paper records.
FAQs: **Storing Consents in Medical Records**	How to store signed research consent and assent forms in subject's medical records