Study Management

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This section includes Clinical Trial study management tools, templates, and guidance for investigators conducting clinical trials. For additional assistance with study management tools, please contact us at ResearchGo.

Before You Begin The Clinical Trial

Protocol Template

A protocol is a document that describes the background, rationale, objectives, design, methodology, statistical considerations, and organization of a trial. The ICH Good Clinical Practice Guidelines specify some topics that should generally be included in a protocol. See the Sample Protocol Template when developing your protocol. Many of the NIH institutes have their own protocol templates. Examples are available at the NIAID website.

Budget Development

Budget development involves three components:

1. Identifying the cost of all research items and services required for the study
2. Assigning financial responsibility for all items and services; and
3. Maintaining a process for recovering costs throughout the study.

Every investigator should have a clear financial management plan to adequately support their research endeavors. The plan should include a defined department process and a responsibility log which outlines the team members accountable for the process. Please review Coverage Analysis and Budget before starting your study.

Feasibility Checklist

When approached with an invitation to participate in a clinical trial, the investigator usually receives a copy of the protocol or a protocol synopsis. It is very important to carefully review and evaluate the protocol and determine if the appropriate patient population and resources are available for successfully completing the trial. The Clinical Trial Feasibility Checklist gives you a list of questions that you should consider before agreeing to participate in a clinical trial.

If you are considering an investigator-initiated clinical trial, the Sponsor-Investigator Initiated Clinical Trial Feasibility Checklist gives you a list of questions to consider before initiating a clinical trial.

For Studies using CTRC Services

CTRC meetings are held every other Wednesday. A complete application and all requested documents must be received at CTRCServices@mednet.ucla.edu by 5pm the Wednesday prior to the scheduled CTRC Operations Committee meeting date. An incomplete submission may delay review.

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Study Initiation

Regulatory Binder
The Regulatory Binder contains essential study documents which individually and collectively permit the evaluation of the conduct of the trail and the quality of the data produced. Filing these documents in a timely manner can greatly assist in the successful management of a trial. See the sample Regulatory Binder Table of Contents.

Delegation of Responsibility Log
Conducting a clinical trial is clearly a team effort with every member in the study team playing an important role. However, the overall responsibility for a clinical trial rests with the Principal Investigator. The Principal Investigator then delegates specific responsibilities to various members within the team. These responsibilities should be formally assigned. The Delegation of Responsibility & Staff Signature Log helps track the responsibilities of the various team members.

Study Flowsheet
For some studies creating simple reminders or worksheets will help staff obtain the required data in a timely fashion and greatly helps in reducing the number of missing data points. The Study Flowsheet can serve as a reminder to ensure that all protocol specific procedures are completed in a timely manner.

Schedule of Assessments
The protocol should clearly outline the activities that are to be performed for the research study. This includes a plan for administration of study treatment and a list of assessments and procedures that are to be performed for the duration of the study. The Schedule of Assessments lists all the study related activities and the time points at which they should be performed.

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Master Subject Log
Most clinical trials involve multiple study visits over an extended period of time. While it is very important to maintain subject privacy and confidentiality, a study coordinator's job also involves making sure that subjects come for their follow up visits on schedule. A study coordinators job is made much easier to have all the subject contact information in one place. In conjunction with the Subject Visit Schedule Log. the Master Subject Log helps to make the study coordinators job a bit easier.

Subject Screening and Enrollment Log
Usually a research team has to screen several subjects to find subjects who are eligible for participation in a particular study. No subject may be screened without informed consent, unless this was waived by an IRB. It is important to keep

track of all the subjects who agreed to participate in a research study by signing the informed consent form. Some of these subjects may be screen failures, some may withdraw after a few visits while others go on to complete the study. The Screening / Enrollment / Withdrawal Log helps track study subjects.

Subject Visit Schedule Log
Most coordinators work on several studies simultaneously. It is very difficult to keep track of subject visits especially when studies involve multiple visits over long periods of time. The Study Events Tracking Form and Subject Visit Log will help you keep track of subject visits and will also help you calculate subsequent visits.

Case Report Form (CRF) resource from NINDS

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Tracking and Reporting

Adverse Event Tracking

At every study visit, the subject should be observed for adverse events and should be asked about any adverse event that might have happened since the previous visit. Most of these adverse events might not meet the definition of an Unanticipated Problem Involving Risks to Subjects or Others. All study events need to be tracked meticulously in an Adverse Event Tracking Log. See IRB Post-Approval Reporting for additional guidance.

Protocol Deviation Information

Although it is important to follow the protocol very strictly, deviations do sometimes occur due to various reasons. Some protocol deviations might meet the definition of an Unanticipated Problem Involving Risks to Subjects or Others. The Protocol Deviation Tracking Log tracks all the protocol deviations and serves as documentation of the determination of whether or not a particular deviation should be submitted to the IRB. See the OHRPP Violation Incident Guidelines for additional guidance.

Note to File

A Note-to-File may be written by any member of the study team to provide additional information or clarification.

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Accountability Logs

Device Accountability Log
Investigators are responsible for maintaining strict control over investigational devices to ensure that the device is used only for subjects enrolled in the study. The Device Accountability Log helps maintain study device inventory and can be included in the regulatory binder.

Drug Accountability Log

Investigators are responsible for maintaining strict control over investigational drugs to ensure that the drug/biologic is used only for subjects enrolled in the study. The Drug or Biologic Dispensing/Accountability Log helps maintain an inventory of drugs used during the study and can be included in the regulatory binder.

Specimen Log
Safety laboratory assessments are usually part of most clinical trials that involve an investigational test article. Biological materials might be sent to the local laboratory or to a central laboratory. The Specimen Log helps track samples that are collected from study subjects.

Additional log resources can be found on the Partner's Healthcare website here.

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Quality Management Practices

Ideally, every clinical trial should have a Clinical Trial Quality Management Plan (QMP) describing the tools that will be used to ensure study quality. The extent and nature of monitoring may be determined based on various considerations such as trial design, complexity, size, risks to subjects, and endpoints of the trial.

One of the benefits of developing and implementing a QMP includes developing proactive communication among clinical trial team members. This benefits clinical trial teams by encouraging early identification and resolution of clinical trial problems and concerns. Implementing a Clinical Trial QMP can also encourage conformity with Standard Operating Procedure, Good Clinical Practice (GCP), Good Laboratory Practice, and UCLA policies and procedures. This leads to an overall reduction in external (Sponsor, FDA) and internal (UCLA) data queries, and helps reduce clinical trial closeout time.

Quality Management Plans include all the activities undertaken to verify that the requirements for quality of the trial related activities have been fulfilled. Listed below are several logs and checklists that might help with quality management plan development:

- Chart Audit Tool
- Regulatory File Review Tool
- Monitoring Log

Industry sponsored clinical trials usually have a comprehensive monitoring plan. Regular monitoring of a trial is very helpful to verify compliance of the trial with currently approved protocol, Good Clinical Practice and applicable regulatory requirements.

Source Data are defined as all information in original records or certified copies of clinical findings, observations, or other activities that are necessary for reconstruction and evaluation of the trial. The records that contain source data are called Source Documents. Source Document Verification is an important part of monitoring. Source data is verified by reviewing that all the data variables in the case report form accurately reflect information in the source documents.

Researchers may choose any option that is appropriate for the trial, some of the options include; a review of all data variables in the case report form for all enrolled subjects, a review of all CRF data for a percentage (e.g. 5%) of patients enrolled or even a review of only certain specified variables on all or some CRFs (for example, only the eligibility criteria).

?Essential Documents permit evaluation of the conduct of a trial and the quality of data produced. These documents serve to demonstrate compliance with standards of Good Clinical Practice and with all applicable regulatory

requirements. Filing these documents in a timely manner can greatly assist in the successful CTQMP and management of a trial.

- Sample Quality Management Plan
- Sample Clinical Quality Management Regulatory File Review Tool
- Food and Drug Administration (FDA) Regulations
- Commonly Used QM Definitions

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