# Study Management Tools

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.

Need assistance or have clinical study management questions? Please contact ResearchGo.

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