



Budget Development Basics for Research Studies

Protocol Review

Before developing any sort of budget for a study, the Investigator should carefully read the protocol for the particular study. During this read-thru, Investigators should take notes of the actual procedures called for in the text of the protocol. It is also critical for Investigators to identify issues and procedures that may arise during the protocol that are above the ordinary standard of care. This is important not only for budget development and negotiation but also for Medicare Coverage Analysis. Often times, after the text of the protocol, the Sponsor lists in table format a Summary or Schedule of Evaluations for the study (if there is no table of evaluations in the protocol then the Sponsor has likely submitted it separately as part of the Sponsor Developed Budget (“Sponsor Budget”). Investigators should compare their lists of procedures to the schedule of evaluations and note any discrepancies and items that are above the standard of care.

Internal Budget Development

It is best to develop an internal budget first before contacting a Sponsor about the Sponsor Budget. There are numerous costs that might be beyond the scope of costs submitted in the Sponsor Budget. Investigators are encouraged to contact the Office of Research for assistance in developing the internal budget to cover the costs of the study. The Research Budget Template located on the “[Forms](#)” [Webpage](#) may be utilized to help with the internal budget development. Internal Budgets should also identify and address the discrepancies and items/services that are above the standard of care.

Generally, there are (i) Direct Costs including salaries, hospital costs, supplies, equipment, procedures, pass-through, etc. and (ii) Indirect Costs, sometimes called overhead (indirect costs are a percentage of the direct costs). “Pass-through” costs, although not directly related to patient enrollment or treatment, are direct costs to a study. These costs include start-up costs, IRB review and amendment fees, pharmacy start-up, advertising, screen failures, etc. Often, Sponsor Budgets fail to identify all the direct costs, especially the pass-through costs, so it is important for Investigators to identify or work with the Office of Research to identify all costs associated with a study.

Sponsor Budget

The internal budget should now be applied to the Sponsor Budget so that the additional costs and expenses identified are presented to the Sponsor in a familiar format. Be prepared to justify all additional expenses captured to the Sponsor.