Research paper on budget checklist - clinical research operations

Literature, Russian Literature

The preparation of a budget

The preparation of a clinical trial budget is a team based undertaking that not only requires the input of those who are conducting the study but also consultants (Benson, 2009). Coming up with a budget entails the consideration of three types of costs: direct costs, opportunity costs and indirect costs. The direct costs are the costs that are specifically related to the study that is being conducted (Woodin, 2004). Indirect costs are the costs are used for the facilitation of the necessary infrastructure for conducting the study. Examples of indirect costs are rent, internet charges and insurance. Opportunity costs on the other hand represent the returns accrued in the course of conducting the study that could be invested in other ways in order to generate income (Kelly & Hart, 2009). There are certain factors that ought to be considered in coming up with a budget. Below is a brief overview of some of these factors.

Factors to Consider while Preparing Budgets for Clinical Research Operations

The research team: It is important for the researcher to determine the number of staff who will be required during the clinical trial, their qualification and the duration of time they will be working for (Kelly & Hart, 2009). Staff costs include: salaries, health insurance, taxes and other forms of compensation such as holiday compensation and pension. It may also be necessary to hire consultants such as accountants, photographers or security personnel in the course of a clinical trial (Baer, Devine, Beardmore, &

Catalano, 2011). The percentage of billable hours ought to be calculated in order to compensate for the work done by the staff.

The protocols that shall be used during the clinical trial: The researcher ought to consider the type, the acuity, phase and the complexity that will be used in the course of the trial (Woodin, 2004). Safety, ethical, legislative and consistency issues are some of the issues that could arise in the course of a clinical trial which could incur costs. Protocols that give rise to inconsistent results could result in inflated costs while unsafe protocols may result in legal action (Woodin, 2004). In addition to this, unsafe protocols could render the results of the clinical trial void thus wasting time and resources of the researcher and those who participated in the study. The researcher needs to determine the tests that will be carried out and evaluate their efficacy and necessity versus the amount of funding that is available (Rainey, Baker, & Jameson, 2007). The pieces of equipment that will be used also ought to be factored in so as to determine whether there is need to purchase them or utilize existing ones at an institution or a hospital.

The duration of the clinical trial: The duration determines the amount length of the clinical trial which directly translates to the amount of money spent (Baer, Bechar, Cohen, & Devine, 2010). The follow up time on resources is also an important parameter that should factored in the budgeting process.

The standard of care: This refers to “ the degree of care that is required by an individual who is under the duty of care (Baer, Devine, Beardmore, & Catalano, 2011).” It is a requirement placed by the law upon individuals who

are undertaking any activity that poses potential harm to others. The ethics committee ought to be consulted prior to conducting a study in order to determine the proper standard of care. The standard of care also spells out the rights of the study subject. Any breach of standards of care could lead to legal action (Rainey, Baker, & Jameson, 2007).

Contingency costs: Even in the most well designed research projects, there are always eventualities that were unforeseen. The subjects could develop an adverse reaction to a drug, equipment could break down or a procedure might have to be revised. Having an allocation for contingency takes care of such occurrences (Kelly & Hart, 2009). It could be 10% of the total budget or even more depending on the type of clinical trial being undertaken.

Coverage by Medicare: In the USA, there are requirements by the law guiding researchers on how to bill Medicare. The researchers should make inquiries and consult an expert on the due process. It is worth noting that all clinical trials can bill Medicare for the costs incurred (Rainey, Baker, & Jameson, 2007). There are steep fines for billing errors, double billing and any form of fraud revolving around Medicare.

Standard of care analysis

Determine the care that will be accorded to the study subjects.

Avoid a legal suit for breach of standard of care

Contingency costs

Meet any costs that were not initially foreseen

Protocols

Spells out the tests that will be carried out and the necessary equipment

Duration of the trial

Determines the % billable hours of the staff

Composition of the research team

Determines the amount that will be spent on personnel

Coverage by Medicare

Determines what the researcher can claim from Medicare

References

Baer, A., Bechar, N., Cohen, G., & Devine, S. (2010). Basic Steps to Building a Research Program. J Oncol Pract. , 45-47.

Baer, l. R., Devine, S., Beardmore, C. D., & Catalano, R. (2011). Clinical Investigator Responsibilities. J Oncol Pract. , 124–128.

Benson, L. (2009). Developing Clinical Research Budgets. Socra Source , 65-69.

Kelly, L., & Hart, R. (2009). Budgets for Clinical Trials. In K. Woodbury-Harris, & B. Coull, Frontiers of Neurology and Neuroscience. Karger: Basel.

Rainey, J. M., Baker, L. H., & Jameson, S. (2007). Prepare and Plan for Financial Constraints on Clinical Trials. J Oncol Prac , 37-38.

Woodin, K. (2004). Preparing for a Study. In S. Gambrill, The CRC’s Guide to Coordinating Clinical Research (pp. 94-98). Boston: CenterWatch.