

	<b>Standard Operating Procedures</b>
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Procedure Category:	Protocol Review
Procedure CLN-01-05:	Assessing the Financial Aspects of a Study

**Procedure Overview**

This procedure defines methodology for assessing the financial aspects of a study by analyzing the costs, revenue and other related factors.

**Responsible Individuals**

Investigators; Qualified MICHIR personnel; Director, MICHIR

**Procedure**

This process includes assessing the required study procedures, the personnel required, the time required, access to the patient population, the proposed budget, facility overhead, potential future studies and the impact of potential publications.

The following general questions need to be addressed to assess the financial aspects of a study.

1. Does the proposed budget include all anticipated costs of conducting the study?
2. Does the reimbursement level in the proposed budgeted adequately cover each anticipated costs?

The investigator and/or designated MICHIR personnel reviews the protocol in detail to assess each of the following areas relating to cost and profit.

- What types of procedures are required within the protocol?
- Will outsourcing be required to conduct the study?
- What staff will be required to conduct this protocol?
- Can current staff conduct the study or will new staff be necessary to conduct the study?
- Will consultants need to be utilized during the study?
- How long is the study?
- Are costs likely to change over the duration of the study?
- How much time will staff need to spend on this study?
- Are additional costs likely to ensure that patient enrollment objectives are met

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- Is there potential to be involved in future studies with this sponsor? If, so does this potential affect the financial considerations?
- Is this a pivotal study for the investigational product? If so, does this affect the financial considerations?
- Is it likely that publications associated with this study will affect the study site? If so, does this affect the financial considerations?
- Will there be advertising costs?
- Will there be indirect costs?
- Will there be nonrefundable startup payments?

The budget must be carefully reviewed to answer the following questions:

- How do the proposed budget amounts compare to the estimated expenses?
- Does the proposed budget cover all anticipated additional costs?
- Is additional funding provided for patient recruitment efforts, if needed?
- Are enrollment incentives included in the budget?
- Does the budget cover estimated overhead?
- Are budget negotiations possible and are these negotiations likely to remedy any deficiencies in the proposed budget?

Each of these points must be addressed to determine if the study can be conducted in a financially sound manner. Keep in mind that sponsor payments to individuals are not allowed and staff cannot accept enrollment bonuses or incentives.

### **Documentation**

Documentation includes the study protocol, the proposed budget, information used to estimate costs and documentation related to budget negotiations, if applicable.

### **Deviation Approval**

The Director, MICHIR or designee, must approve deviation from this procedure. The Director, MICHIR or designee, must store documentation of the deviation approval.

### **Procedure Author**

Manager, Research Support Core

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