**Reviewing the Protocol for Financial Impact**

***SOP*** FM XX.XX

***Approval:***

 ***Approved by Date***

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| **Instructions for modifying this template:** 1. This is a template and should be used as such. Please use this in the manner most appropriate for your research unit.
2. Anything in this template can and may be modified as appropriate for your area while accounting for your interpretation of the most current FDA Guidance.
3. After you have modified this SOP template, do not forget to remove the “**Instructions for modifying this template**” table.
4. Number the SOP using you own guidelines for numbering.
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**I. SCOPE/PURPOSE** The scope of this SOP is to describe how to review study protocols for activities that will affect the study budget. The purpose of this SOP is to provide guidance to UAB research sites in conducting a protocol review and to understand its impact on development of a study budget. This SOP will describe the review process and its implementation.

**II. ALLOWABLE EXCEPTIONS**

This SOP will be adhered unless exceptions are required. Exceptions will be noted in a formal note to file (see relevant SOP).

**III. RELEVANT REGULATIONS/GCPS**

University Accounting requirements

**IV. DEFINITIONS/ACRONYMS**

SOP Standard Operating Procedure

CRO Contract Research Organization

CRU Clinical Research Unit

CRFs Case Report Forms

eCRFs electronic CRFs

IDS Investigational Drug Service (research pharmacy)

TKC The Kirklin Clinic of UAB Hospital

**VI. RESPONSIBLE PERSONNEL**

Protocol review is to be conducted by key staff involved in the conduct of the study. This includes, but is not limited to, Study Coordinator, Data Manager, Unit Manager, Finance staff, Pharmacy staff, and others as needed.

**VII. DETAILS**

The following is a description of how the protocol review process should proceed.

1. Protocol Review
2. Obtain study protocol.
3. Determine if the protocol version is the Final version. It is preferable to use a Final version to preclude the need for revisions during initial budget development.
4. Begin the review by reading the Protocol Summary. This summary gives a brief description of the overall study flow.
5. Read the Schema/Schedule of Events (also sometimes called Schedule of Assessments) including applicable footnotes.
	1. The Schema/Schedule of Events provides the framework for line item activities to be listed in the detailed budget.
	2. In addition, the Schema/Schedule of Events identifies the visits in which each activity occurs.
	3. Some activities will be clinical billable items. Other activities will be performed by UAB research site staff or ancillary department staff as study services.
6. Read the Treatment and Assessment Sections of the protocol. These sections describe in more detail the activities listed in the protocol schema.
7. Read information presented for previous studies. These data may provide insight into side effects/safety concerns that could affect estimates of staff effort.
8. Protocols typically include figures, tables, and appendices. For budget development purposes look for figures, tables, and appendices that provide plans/schedules for billable activities such as special sample collection plans and multiple ECG collection plans.
9. Read sections related to monitoring for information on monitoring frequency and on-site vs. remote monitoring.
10. Read the data collection section regarding Case Report Form (CRF) completion and submission processes. There is a cost variance between paper CRF completion/submission and that for electronic CRFs. Training may be required for eCRF systems.
11. Any protocol review for budget development should be supplemented by a review of the Informed Consent Form, draft contract/budget, and study manuals. The visit schedules and requirements should match between all documents reviewed. If they do not match, send questions to the sponsor/CRO for clarification.
12. Review of the protocol and supplemental documents should provide the answers to What (activities to be performed) and When (visit schedule). The next step is to define Who (Provider) and Where (Location) of each activity. Discussion with the Research Study Team, Principal Investigator and applicable departments will ensure that appropriate answers to these questions are acquired.
13. The novice reviewer may find it helpful to use tools to assist in compiling/tracking information relevant to budget development. Examples of such tools are highlighting protocol text, developing an activity list as the review process proceeds, and keeping track of questions that may need to be presented to the Sponsor/CRO and/or Principal Investigator/Research Study Team.

General Per Patient Budget Categories to consider during the protocol review include, but are not limited to:

* Pharmacy (e.g., TKC, IDS, nuclear)
* Treatment
* Laboratory
* Biological Sampling
* Procedures
* Office Visits
* Study Services (Manpower, or labor, activities performed by staff of the UAB research site and not considered clinical billable activities. Examples of such activities include data management, study coordination, and PI oversight.)
* Inpatient Hospital stays
* Follow Ups
* Patient stipends

General Study Level Site Costs to consider during the protocol review include, but not limited to:

* Start-up Activities
* Protocol Amendments
* Ongoing Regulatory Activities (IRB reporting/study renewal, FDA 1572/document updates, etc.)
* Labs/Procedures/Tests that are either optional or driven by specific clinical criteria
* Unscheduled Visits
* Teleconferences
* Ongoing Training
* Hotel Stays
* Travel reimbursement
* SAE Reporting
* Archive Storage
* Close-out
* Re-Consenting
* Pre-Screening
* Shipping and Handling
1. Impact on Study Budget
2. In developing a study budget, it is important to have an accurate picture of what will occur at each study visit. Once a complete list of activities is developed for each visit, location for all services can be determined. This detailed analysis allows development of an accurate budget.
3. An important element of the protocol review is the assessment for activities that will impact manpower needs for the study. Some of the manpower assessments are ‘inferred’ from information obtained during the protocol review process. Examples include specific data to be captured on the CRFs, use of study questionnaires, or details for processing biologic samples.
4. To ensure a comprehensive and accurate budget is developed, it is important to involve all relevant staff in the protocol review and budget development process.
5. Archival of Review Records
6. It is recommended that a record of the protocol review be maintained with study budget development records. Should anomalies arise during the conduct of the study, reference can be added to the review record. This will then become reference material to build upon for future use.
7. Archived budget development records will be useful backup for audits.
8. Archival methodology is at the discretion of the UAB research site.

**VIII. QA**

 NA

**IX. APPENDICES/RESOURCES**

Appendix A – Protocol Review Checklist, Per Patient Budget Considerations

Appendix B – Protocol Review Checklist, Study Level Budget Considerations

**X. RELATED SOPS**

NA

**APPENDIX A**

**PROTOCOL REVIEW CHECKLIST**

**Per Patient Budget Considerations**

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| --- | --- | --- |
| **Reviewed** | **Budget Category** | **Notes/Questions** |
|  | Laboratories |  |
|  | Biologic Sampling |  |
|  | Procedures |  |
|  | Treatment |  |
|  | Pharmacy (IDS, TKC, Hospital, Nuclear) |  |
|  | Office Visits |  |
|  | Inpatient Hospital Stays |  |
|  | Follow-up Visits, Telephone Calls, etc. |  |
|  | Study Services (Manpower, or labor-related activities) |  |
|  | Unscheduled Visits |  |
|  | Drug/Device Profile Affecting Safety Reporting |  |
|  | Need for Hotel Stays, Travel Reimbursement |  |
|  | Teleconferences |  |
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**APPENDIX B**

**PROTOCOL REVIEW CHECKLIST**

**Study Level Budget Considerations**

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| --- | --- | --- |
| **Reviewed** | **General Study Level Activities** | **Notes/Questions** |
|  | Start-up Activities |  |
|  | Protocol Amendments |  |
|  | Ongoing Regulatory Activities |  |
|  | Safety Reporting, Handling |  |
|  | Initial Training Requirements |  |
|  | Ongoing Training Requirements |  |
|  | Re-Consenting |  |
|  | Pre-Screening |  |
|  | Shipping, Handling |  |
|  | Close-Out Activities |  |
|  | Archival Storage Requirements |  |
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