***TITLE: Budget and Contract Process***

***SOP Version #***

***Author(s):***

***Approval:***

 ***Approved by Date***

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**I. SCOPE/PURPOSE** The scope of this SOP is to describe how the clinical trial budget and contract process will be developed and managed by UAB research sites. The purpose of SOPs is to assure consistency and rigor with the design, conduct and implementation of clinical trials at UAB by providing standards and guidelines for the staff. This SOP will describe the development and implementation of SOPs by the CTO Research Group SOP Committee.

**II. ALLOWABLE EXCEPTIONS**

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

**III. RELEVANT REGULATIONS/GCPS**

Sunshine Act, UAB F&A Agreement, National Coverage Determination (NCD 310.1), Affordable Care Act

**IV. DEFINITIONS/ACRONYMS**

CTA Clinical Trials Agreement

CTO Clinical Trials Office

CRO Clinical Research Organization

CMS Center for Medicare Services

FAP Fiscal Approval Process

SOP Standard Operating Procedures

**VI. RESPONSIBLE PERSONNEL**

Department Chair/Dean

Department/Division Administrator

Finance Administrator

Coordinator(s)

**VII. DETAILS**

The following is a description of the Budget and Contract Process

1. Building the Budget
2. The study sponsor should provide the budget or a budget template. Budgets are then presented to research sites by the study sponsor or a designee (i.e. CRO). It is typical for a sponsor to present a draft budget to candidate sites at an early stage of site recruitment. The process of qualifying a site and the effort required to execute a site contract can be lengthy and time consuming. Therefore, it is best to know early in the process if the site feels that the study budget is in the “ballpark”. The budget is ultimately tied to a contract or clinical trial agreement which legally describes what is expected from the investigator and institution. The contract will also include details of how and when the site will receive payments for study related activities.
3. A best practices approach is to develop an internal budget in conjunction with the sponsor provided draft budget which identifies study costs based on labor and research rates for procedures. Some departments may require a Protocol Feasibility and/or a Coverage Analysis to obtain internal approval and to incorporate into the internal budget.
4. Coverage Analysis (CA) – a uniform method of analyzing the items and services provided in a clinical trial to determine if that item or service can be appropriately billed to Medicare and other insurers. Such an analysis, when completed prior to study start and formally documented, can help provide a more accurate assessment of study costs for budgeting purposes; avoid submission of incorrect claims (protecting an institution from violations of the False Claims Act); identify non-covered study costs; and assist in the accurate coding of covered charges on billing claims.
5. Whether you are developing your own budget or the sponsor presents you with one, your clinical study budget should cover all study-related costs including fees and indirect costs. In addition, you should ask whether other study-related costs will be paid, such as

• Up-front, non-refundable payment to defray the cost of start-up work such as preparing regulatory documents, attending investigator meetings, site initiation training, enrollment efforts, etc.

• Payment for close-out costs in the case of early termination by the sponsor

• Invoicables to the trial such as related patient travel expense, lengthy monitoring visits, FDA audit, qualifying images/image transfers, file management, adverse events, etc. (yearly or per occurrence)

• Per Patient Costs

• Screen failures

• Prorated payment for subjects who are terminated, drop out, or are lost to follow-up

The first three categories are based on the anticipated time and expense to conduct these activities. Per patient costs are composed of protocol-related procedures and hospital services. To determine what is payable by the study and what is payable by insurance, refer to the Coverage Analysis and incorporate correct line items in the per-patient budget. Once internal costs are estimated, use this as a reference to negotiate the external budget with the study sponsor. The final contract budget will reflect the negotiated rates that the sponsor will pay.

1. To build a budget the following information is required:

• Schedule of Events. The schedule of events describes all of the study related procedures and assessments to be performed per the protocol across a defined visit schedule.

• Staff Salary Estimate (principal investigator, study coordinator).

• Facility billing codes and payment rates for tests and procedures occurring in a facility.

• Physician billing codes and associated payment rates for tests and procedures performed by the physician.

• Estimated Overhead (please reference UAB’s F&A Agreement and/or Department Overheard Policy) [F & A Rate Agreement](http://financialaffairs.uab.edu/img.asp?dl=1&id=33794)

• FAP Submission (inflate FAP prices by 5-10% annually)

1. With the study related tasks organized across a defined visit schedule, the first step in creating the actual budget numbers is to identify the procedures that have established billing codes. For these procedures (i.e. MRI, Labs, etc.) document the average payment level that corresponds with the code that describes the procedure or service. Because Medicare is the only payer which provides their fee schedule, regulations and policies as public information, the Medicare National Average Payment is frequently used as a baseline to establish the estimated payment levels. The elements to calculate the Medicare payment levels are published annually in the Federal Register and can also be found at the Centers for Medicare and Medicaid Services website (cms.gov). The rules and regulations are organized by site of service (Hospital Inpatient, Hospital Outpatient, Physician, etc.). If the majority of the participants in your study will be under 65 years of age and thus eligible for commercial insurance, inflating the Medicare fee schedule would be appropriate.
2. Account for unexpected events (review institutional and department policy regarding residual accounts)
3. Some study-related tasks will not have a corresponding Medicare fee schedule (i.e. informed consent, adverse event review, etc.). For these procedures, you should develop the cost estimate based on the resource(s) expected to perform the task (i.e. physician and/or coordinator) and the anticipated amount of time required to complete the task. Next, you need to decide on an hourly rate for the assigned resource. For example, the process of obtaining informed consent requires time from both the research coordinator and the principal investigator. Let’s assume that the consent process requires 30 minutes of the study coordinator’s time at an hourly rate of $60 and 10 minutes of the principal investigator‘s time at an hourly rate of $300. Therefore, $80 would be budgeted for the cost of the informed consent.
4. It is important to document all of your assumptions so you can easily reference them if needed during conversations with research sites.
5. It is also necessary to differentiate procedures and services which are considered standard of care and those which are not. Procedures and services routinely performed as a part of the treatment or care plan are considered standard of care; those that that are done solely to support the research objective are not. The costs associated with the procedures and services which are a direct result of the research are the responsibility of the sponsor; those that are considered standard of care are billed to the payer. The interpretation of what is standard of care during a clinical study may vary by payer/provider, not the sponsor.
6. Once the study induced costs, salaries, and overhead have been consolidated into one worksheet, the overall cost per patient can be calculated with and without an overhead assumption. Prior to talking with the sponsor, it is also important to plan for the implementation of the payment terms. Will the payment schedule be monthly, quarterly, or based on completed and monitored case report forms? Will an invoice from the site be required? It is important to plan payment schedules in advance so sites know what to expect.
7. Budget Negotiation & Completion
	1. Department research administration provides the study budget to the sponsor along with justification documents and commences with budget negotiation, if required. The budget may be revised through negotiations with the sponsor until both sponsor and research group come to agreement on the study costs. Once negotiations are finalized, research administration enters negotiated costs into new version of the budget and submits this to OSP to incorporate into the CTA.
8. Negotiation of Specific Terms
	1. Some of the terms most commonly included in a CTA are set forth below. This list is not intended to be comprehensive and does not capture every provision that may be found in a CTA, which will depend on the form provided by the individual Sponsor. The Institution’s preferred position with respect to the following areas is outlined below:

• Data/Results;

• Device Supply, Device Fees and Payment Terms

• Intellectual Property;

• Enrollment Goals;

• UAB IRB/WIRB Fees

• Exceptional Compensation Related to Enrollment

• Publication;

• Payment Schedule and Payment Terms;

• Invoicing

• Confidential Information;

• Indemnification/Insurance;

• Warranties/Limitation of Liability;

• Subject Travel Expenses

• Termination

1. Negotiation of Miscellaneous Terms;
	1. A few of the other standard provisions that are frequently seen in CTAs and which typically do not require extensive negotiation include, among others:

• Requirement on the part of the Institution to abide by Good Clinical Practice (FDA regulations)

• Requirement to obtain ICF/HIPAA authorization from subjects (required by Privacy Rule established by HHS under HIPAA)

• Debarment of, or other sanctions imposed on, Study personnel

• Inspection/audit of the Trial by the Sponsor

• Governmental inspections

• Notification of adverse events

• Retention of Study records

• Publicity restrictions

• Registration on clinicaltrials.gov

1. Contract Process
	1. The first step in the contracting process is receiving a draft contract from the potential sponsor as a Word document. Additionally, as a general reference for sponsors, UAB’s Office of Sponsored Programs (OSP) provides a guideline document, “UAB Contract Language Guidelines for Industry Sponsors of Clinical Trial Agreements” that can be accessed through its website ([www.uab.edu/osp](http://www.uab.edu/osp)) via the “Research’s Toolkit” link. The Principal Investigator (PI) as well as a designated Department Administrator, and any other appropriate staff, should read through the contract and understand the commitments/obligations. After review and Departmental approval, the contract should be sent via e-mail to OSP at osp@uab.edu. When e-mailing the contract, in the subject line of the e-mail, include the PI’s name, the sponsor’s name and the project title. In addition, when submitting the contract for review, a copy of the protocol and informed consent form should also be submitted to OSP. Other items may also be required at the time of submission (please see “CPAP – Navigating the Clinical Protocol Activation Process for Industry-Written and Sponsored Clinical Trials” located on the OSP website in the “Researcher’s Toolkit” section). At the same time, the Department should also fill out an “Extramural Support Checklist” and a “Responsible Personnel List” (accessed through OSP’s website) and submit hard copies with appropriate signatures to OSP. The budget does not have to be finalized at this stage. The “Requested Funding” and “Requested Project Period Dates” of the “Extramural Support Checklist” may be left blank when initially submitting.
	2. After the budget has been finalized, it should be forwarded to OSP.
	3. The contract officer at OSP will be the point of communication with the sponsor during the contract negotiation phase. Once an agreement has been reached on contract wording, OSP will forward a final version of the contract to the Department. The PI as well as a designated Department Administrator, and any other appropriate staff, should read through the final contract and understand the commitments/obligations. If approved by the Department, the PI will sign the contract and send it back to OSP. The contract will then go through the final execution process.

**VIII. QA**

 NA

**IX. APPENDICES**

**Appendix A – Research Protocol Start-Up Flow Chart**

**X. RELATED SOPS**

**NA**