

## POLICY AND PROCEDURE MANUAL

<b>Pennington Biomedical</b>	<b>POLICY NO. 301.00</b>	<b>Origin Date: 12/01/2008</b>
<b>Impacts:</b>	<b>CLINICAL RESEARCH</b>	<b>Last Revised: 02/10/2012</b>
<b>Subject:</b>	<b>CLINICAL STUDY BUDGET FACILITATION &amp; INITIATION POLICY</b>	<b>Effective: 03/01/2013</b>
<b>Source:</b>	<b>ASSOCIATE EXECUTIVE DIRECTOR FOR SCIENTIFIC AFFAIRS and CSO</b>	<b>Version: #6</b>

### **PURPOSE**

To establish a procedure that insures that all Cores and Laboratories (hereinafter collectively referred to as “Units”) of the Pennington Biomedical Research Center (PBRC) receive copies of Clinical Trial Protocols prior to contract negotiations with third parties (NIH, Pharmaceutical companies, food companies, pilot and feasibility, division funds, etc);

To assure that all Units have an opportunity to provide assistance with study logistics in the planning phase; and

To assure that all services can be provided by Units; and

To assure that the study procedures can be achieved within reasonable budgetary means; and

To assure that budgets are congruent with the protocol, and comply with federal sponsor requirements; and

To facilitate study initiation and schedule clinical trials to start.

### **DEFINITIONS**

**Clinical Trial** – For the purpose of the application of this policy, clinical trials are defined as the controlled, clinical testing in human subjects of investigational new drugs, devices, treatments, or diagnostics, or comparisons of approved drugs, devices, treatments, food products or diagnostics, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes.

### **PROCEDURES**

1. It is the responsibility of the Principal Investigator to assure that all Units are provided with information on the study protocol in a timely manner, in order for the logistical and budgetary needs of the study to be assessed and met.
2. All protocols, including those with a pre-determined/external budget will be reviewed by each Unit to determine budgetary needs and routed back to Sponsored Projects for the final collation and approval, first by Sponsored Projects and then by the Principal Investigator.

3. An e-mail group entitled “Clinical Trials Unit Head” will be established and will include Unit Heads, or their proxies from all areas involved in clinical trials at PBRC. Units will be responsible for ensuring coverage over vacations/other absences and must respond to logistical and budgetary issues in a timely manner, generally within 5 working days.
4. The Principal Investigator or his/her designee will upload the protocol to Sponsored Projects. This will generate an automatic email that will be sent to all Units and proxies for budget upload. Sponsored Projects will assign a Proposal Number to each protocol (designated as SP Proposal Number FY-xxx).
5. Revisions/modifications to the protocol must be re-routed under the same SP Proposal Number. Protocols on hold (e.g. negotiations stalled, no funding source available, etc.) for one year or longer must also be re-routed.
6. Projects which include a clinical trial protocol, regardless of the location of any/all of the clinical work, must also be routed for Unit review and budget assessment. While some/all clinical testing may occur offsite, there may still be Unit costs involved in the overall conduct of the project.
7. Each Unit will review the protocol [in less than one week] and will upload a study budget under the Budget Acknowledgement screen in the Sponsored Projects routing system. If the Unit requires no budget they will respond “NO” under the Budget Acknowledgements page in the Sponsored Projects system. If the Unit does not respond in the one week time period, there will not be guaranteed funds for the study.
8. The PI and/or project manager/designee may review each budget as they are uploaded and (if necessary) revise the protocol. The PI and/or project manager/designee should immediately notify the appropriate Unit of problems related to the budget.
9. Sponsored Projects will track the protocol and monitor budget acknowledgments.

**Specific Procedures for Pharma/For Profit Sponsors:**

1. After all budget acknowledgments are received, Sponsored Projects will have one week to compile the final composite budget and send it to the PI for review and approval.
2. Sponsored Projects will include a 10% PI oversight fee in all fee-based budgets for private sponsors. The PI may increase or reduce the 10% oversight fee at his/her discretion.
3. Deviations from the Unit budgets must be approved by the Associate Executive Director for Scientific Affairs and CSO and the written approval kept on file in Sponsored Projects.
4. Sponsored Projects will forward final budget with per visit totals only to potential sponsor. If the budget is based on a draft protocol, the sponsor will be informed that the budget is an estimate, and the final budget will be determined upon receipt and review of

the final protocol. Sponsored Projects will not approve agreements for signature until the final protocol has been routed for final budget development.

5. Funds will be distributed to Units according to the budgets submitted during this process and the work performed during the trial. Any funds received in excess of the Units budgeted needs will be allocated to the study PI. The PI may, at his or her discretion, allocate excess funds for particular needs and/or procedures to a specific Unit.

**Specific Procedures for Federal/Non-Profit Sponsors:**

1. Protocols for NIH/Other Federal/Non-Profit sponsors are routed in the same manner as for Pharma/For-Profit sponsors.
2. Unit Heads must upload time & effort (T&E) based budgets. In addition, Unit Heads must upload a budget justification for all funds requested. Justification information will be included in the proposal budget at the PI's discretion, and as required by the sponsor. Costs that are not justified may be removed from the budget request.
3. Units that are approved Service Centers (under LSU PS-103) may upload budgets using approved prices/fee schedules.
4. Business Managers will compile Unit budgets and PI budget into a cumulative T&E budget, including appropriate fringe & indirect cost rates.
5. At the request of the PI, Sponsored Projects, Business Managers, PIs and participating Unit Heads will meet to discuss the cumulative budget and protocol. Adjustments will be made as necessary for protocol congruency and/or to comply with sponsor requirements.
6. Sponsored Projects will double check the final budget to ensure all Unit costs are included, and transfer the cumulative budget and budget justification information onto appropriate sponsor forms.
7. Sponsored Projects will route the final proposal and budget for internal approval, and submit to potential sponsor.
8. If funded, accounts will be created for PI and Units according to the approved budget. Funding reductions will be applied equally to PI and Units, or as otherwise agreed upon (i.e. reduction in project scope).

**Specific Procedures for Pilot and Feasibility (P&F) and internally funded projects:**

1. Protocols for P&F and internally funded projects must also be routed for budget development.
2. Unit Heads must upload time & effort (T&E) based budgets. Units that are approved Service Centers (under LSU PS-103) may upload budgets using approved prices/fee schedules.

3. Sponsored Projects will compile the final internal budget. Indirect costs will not be assessed, as P&F projects are funded from existing federal grants or state funds, and internally funded projects are funded using state funds, foundation funds, or expired fixed price accounts where indirect costs have already been recovered.
4. Budgets for approved P&F projects will be forwarded to Business Managers for account establishment.
5. Budgets for internally funded studies will be forwarded to Business Managers, who will work with the PI to identify a funding source.

## **OVERSIGHT**

The Associate Executive Director for Scientific Affairs and CSO and/or his or her designee, and will oversee this policy. Any exceptions to this policy or concerns regarding clinical trial budgeting will be brought to the attention of the Associate Executive Director for Scientific Affairs and CSO, or his or her designee.

**Policy Committee Secretary's Attestation**

Date of Policy Committee Meeting: NA/Expedited Email Approval

Policy #: 301.00 – Clinical Study Budget Facilitation & Initiation Policy

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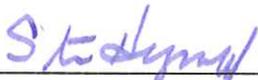


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Anne Duke, Policy Committee Secretary



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Date

**Approval by the Executive Director**



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Steven B. Heymsfield, MD



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Date