



**Departmental Guidelines on budgeting and invoicing for industry-sponsored studies  
5/2/17**

**Goal:**

In an effort to assist investigators preparing budgets for and conducting industry-sponsored studies, to ensure fair use of departmental resources, to help balance department budget by minimizing cost-sharing, and to ensure adherence to University processes, the Department of Pediatrics is putting forth guidelines regarding budgeting and invoicing for industry-sponsored studies. These guidelines are to be followed for all industry-sponsored projects with PI(s) affiliated with the UIC Department of Pediatrics.

**Guidelines:**

**A- Effort**

When budget for a program or project is being prepared, actual effort and corresponding salary/fringes projected for the investigators must be included in the budget. Effort that is expended by investigator, but is not reimbursed by sponsor, is considered cost-sharing and uses department resources. Cost-sharing is to be minimized as much as possible and requires departmental approval.

Minimum level of effort budgeted **for PI (or co-PI)** should be as follow:

- Industry-sponsored trials: 5-10% *minimum*.  
Make sure to include time for administrative tasks (i.e., supervision of study, communication with sponsor) and for performance of study (such as conducting physical examinations for research, writing research notes)

Level of effort listed on budget for an **investigator (co-I)** must reflect actual involvement and effort in the project. The following minima are recommended and may vary based on investigator's role in project:

- Industry-sponsored trials: 3-5%

Note that very small levels of effort (1-2%) correspond to approximately 20-40 hours per year and must be reserved for studies in which investigators have minimal involvement (e.g., assist with design/analysis/interpretation of results, conduct of a few, well-defined procedures, etc.).

**B- Rates for services, care, staff**

Budget originally proposed by sponsor is usually on the low end and should generally not be accepted. Revisions and negotiations are expected and should reflect fair market value for all costs. All costs should be ITEMIZED and DOCUMENTED.

Document market values for all costs, especially during budget negotiations with sponsor:

- For patient-care items/services, Medicaid rates are NOT fair market value (they are well below value). On the other end of the spectrum are the “charges” from hospital. “Fair Market Value” is somewhere between these estimates. → When starting negotiations, list charge prices; sponsor will likely ask that prices be adjusted.
- Similarly, when listing on the budget the services provided by staff, fair market value of services may be used as an estimate (it does not have to be the actual salary of the staff member performing task).
- Difference may be kept as a margin, i.e. the amount remaining after all costs have been charged to the grant (services, efforts, supplies, etc.), as long as margin <20% of total award.

### **C- Start-up costs**

Estimates for all start-up costs must be ITEMIZED and DOCUMENTED.

- Estimate and document market values for all start-up costs, especially during budget negotiations with sponsor. For example, must estimate hours, personnel for preparation time, site visit, etc (pre-study set-up, administration, preparation of IRB documents and revisions/amendments, background, preparation for site visit, etc).
- Make sure that IRB review fees are listed clearly and distinctly from costs incurred for preparation of IRB material. (Note: most pharma budget have a category for IRB fees that is separate from start-up costs).
- To manage margins: charge salaries, etc, as payments from sponsor are received. Make sure to itemize and justify invoices. Difference may be kept as a margin (as long as <20% of total).

### **D- Warning on Double billing of items**

Some procedures and services for participants may also be performed as part of their standard care. Attention must be exercised to avoid billing study sponsor and Medicaid/insurance for the same services.

Although hospital invoices for study procedures are reviewed by nurses, billing to Medicaid/insurance is not. If in doubt, the compliance office may be asked that a hold on billing be observed for the participants, pending review and line-by-line verification of charges.

### **E- Physical examinations**

Sponsor only pays for research activities/research notes (pro fees)

- Make sure documentation (chart, caser report forms, research notes) clarifies standard care vs. research activities.
- All patient visits (including those for research only) must be in Cerner.

#### F- Margins

Margins are the amount remaining on account after all costs have been charged to the grant (services, efforts, supplies, etc.). Margins should be less than 20% of total amount received for the award. For example: if a total of \$200,000 was received as reimbursement from industry (including start up costs, IRB fees, participants incentives, etc.), and \$160,000 was expended (including salary + fringes, travel, patient care, CRC fees, participant incentives), margin is  $(200,000-160,000)/200,000=0.2=20\%$ .

Variance that is too high at closure is likely to result in the study being flagged by OBFS and referred to the compliance office, for the following reasons:

- Tax implications
- Too great a profit for a not-for-profit organization
- May be seen as kickback to investigators (deemed as a red flag; apparent impropriety of a kickback).

**All submissions and pre-submissions that involve budget information or require institutional endorsement must be routed to the ORS through the Department Business Office and obtain institutional approval *prior* to submission to sponsor/funder.**

**No application, regardless of amount of funding requested, should be submitted without approval.**