

CHILDREN'S HOSPITAL AND REGIONAL MEDICAL CENTER
Seattle, Washington

OPERATING POLICIES / PROCEDURES

DEPARTMENT: Office of Sponsored Research

POLICY NUMBER: OSR-12

REPLACES: n/a

EFFECTIVE DATE: November 16, 2005

REVISION DATE: n/a

POLICY TITLE: Industry-Sponsored Clinical Trial Budget Development

POLICY:

The Office of Sponsored Research (OSR) will direct the budget development process for industry-sponsored clinical trials in order to ensure that all associated costs are identified, and adequately reflected in the budget and cash flow terms.

PROCEDURE:

- 1) OSR team will communicate with PI/RN/RC regarding details of the study (verbal discussions with the PI and/or RN/RC will often be most helpful to gain a general understanding of the study and its requirements). OSR team will obtain the following necessary items of information:
 - (a) Electronic copy of final protocol (usually provided by PI or RN/RC). A final version of the protocol is necessary for budget development. Draft versions of the protocol are not acceptable as any changes to the protocol could potentially impact the budget;
 - (b) Verbal or written description of study;
 - (c) Discuss particulars with PI/RN/RC (IRB submit date, anticipated study start date, special conditions or requirements such as use of CRC, unique use of CHRMC facilities, etc.)
 - (d) Any additional pertinent budget information (e.g. Sponsor's budget proposal, if Sponsor has provided to PI/RN/RC).
- 2) OSR will work with budget development RN, who will review the protocol and identify all activities and costs associated with the study.
 - (a) If multiple budget requests are received, OSR will determine order of priority and communicate priority to budget development RN.

- (b) In order to clarify issues regarding the protocol or budget development, budget development RN may communicate directly with PI or RN/RC.
 - (c) Budget development RN will review protocol and identify all associated activities. RN will then enter CDM codes associated with each research procedure.
 - (d) Additionally, RN will estimate research staff time required to perform the research activities, and identify the research staff responsible for each activity.
 - (e) RN will obtain price quotes from service providers (lab fees, pharmacy fees, etc.).
 - (f) If the line item is a unique research service not previously provided by CHRMC, and therefore w/out an assigned CDM code, RN will contact appropriate person for custom pricing (i.e. pharmacy, lab, Business Services, etc.).
- 3) Using the Charge Description Master spreadsheet, OSR will enter CDM prices based on the CDM codes identified by the RN. CDM codes may have multiple associated prices, some listed by department. OSR team will determine which price to use based on which department is conducting the research, and by using an average of the various prices. In some circumstances, it will ultimately be the OSR team's best judgment that determines which CDM price to use.
- 4) OSR team will also convert the time allotted for research staff activities to dollars by obtaining current salary and fringe information for accurate calculation of these line items.
- 5) OSR team will review budget to ensure identification of possible hidden costs:
- (a) Will drugs be dispensed? If so, is dispensing fee entered into each associated visit?
 - (b) Patient reimbursements? If so, are they reflected in the budget at each relevant point in time?
 - (c) Translation fees?
- 6) OSR team will review for inclusion of all associated start up costs:
- (a) PI & RN time for IRB preparation (on average: PI - \$1500, RN \$1000 - \$1500)
 - (b) IRB review fee (\$1,500)
 - (c) Administrative fee (\$850)
 - (d) Pharmacy setup fee. (Standard fee \$1,200. May be higher due to complexity or special requirements. Not applicable to all studies.)
 - (e) CRC setup fee (Standard fee \$1,000. Not applicable to all studies.)
 - (f) Lab setup fee (Average fee \$250-\$300. May be higher due to complexity or special requirements. Not applicable to all studies.)
- 7) OSR team will review budget to confirm it meets institutional requirements:
- (a) Confirm IDC rate is at current federal rate (41% as of 10/01/04 to 09/30/06).
 - (b) Confirm B&O tax is accurately assessed.
- 8) In conjunction with budget development by OSR, PI/RN/RC may develop their own budget independently. OSR will compare the two budgets and clarify/resolve discrepancies.

Final budget determination will reside with OSR in order to ensure that budget meets institutional requirements.

- 9) OSR will compare developed budget to Sponsor's proposed payment.
 - (a) Is Sponsor's proposed payment adequate enough to absorb outyear inflation (minimum 10%)
 - (b) Will Sponsor's payment schedule provide adequate cash flow throughout the study?
- 10) OSR will obtain PI's acceptance of final budget, and obtain PI's signature on internal budget spreadsheet indicating approval.
- 11) OSR will negotiate budget with Sponsor.
 - a) Ideally, the internal budget will be developed prior to IRB preparation and the initiation of contract language negotiations.
 - b) Some Sponsors require budget negotiations to be finalized prior to initiating contract language negotiations.
 - c) If the difference between Sponsor's proposed payment and the estimated costs at CHRMC are too significant to overcome, it may be necessary to discontinue efforts towards initiation of the study. In this event, OSR will notify PI and advise on the situation.

Approved by:



Director, Research Finance & Sponsored Projects 11/14/05 Date