

SEATTLE CHILDREN'S HOSPITAL RESEARCH INSTITUTE

STANDARD OPERATING PROCEDURES / POLICIES

DEPARTMENT: Research Support Services  
POLICY NUMBER: CTM-202  
REPLACES: New  
EFFECTIVE DATE: April 2, 2007  
REVISION DATE: \_\_\_\_\_

POLICY TITLE: Clinical Trial Budget Creation in StudyManager

**POLICY:**

Children's requires all clinical trials to have a budget which appropriately reflects research patient pricing policy requirements per policy CTM-200. Budgets must be generated utilizing the StudyManager software. Children's Office of Sponsored Research (OSR) manages the budget generation process with the assistance of Study Staff, and maintains processes and procedures to ensure that clinical trial proposals are effectively analyzed and that that study information is effectively and accurately translated into associated budgets.

**PROCEDURE:**

- 202.1 Investigator and/or research staff will communicate with Office of Sponsored Research (OSR) Clinical Research Budget Analyst (CRBA) and Contracts Officer regarding details of study. Verbal discussions will often be most helpful to gain a general understanding of the study. The Investigator and/or research staff will provide the following information to the CRBA or Contracts Officer.
- 202.1.1 Electronic copy of final protocol. A final version of the protocol is necessary for budget development. Draft versions of protocol are not acceptable as any changes to the protocol may impact the budget.
  - 202.1.2 Discuss particulars such as IRB approval date, anticipated start date, special conditions/requirements such as the use of CRC, and unique use of Children's facilities.
  - 202.1.3 Other pertinent budget information, such as sponsor's budget proposal.

- 202.2 The CRBA will enter all study procedures into StudyManager to develop the budget.
- 202.2.1 CRBA will perform a protocol analysis as per Policy CTM-201 identifying and determining patient care procedures, research procedures and research infrastructure costs.
- 202.2.1.1 Budgets will be built using StudyManager functionality which contains institutional requirements regarding pricing.
- 202.2.1.2 CRBA will discuss/clarify issues regarding protocol or budget development directly with Investigator and/or research staff.
- 202.2.1.3 CRBA identifies service that needs to be entered into StudyManager. CRBA will confirm whether the service exists in the CDM. If yes, CRBA will provide information to the Research Manager for entry into StudyManager. If no, CRBA identifies service that needs to be entered into StudyManager. CRBA will confirm whether the service exists in the CDM. If yes, CRBA will provide information to the Research Manager for entry into StudyManager. If no, CRBA will provide information about the need for a new CDM to the appropriate Clinical Business Manager who will establish new CDM in accordance with hospital policy. For clarification of the process to create a new CDM, contact the Director of Financial Planning and reimbursement. Once new CDM is established CRBA will provide information to the Research Manager for entry into StudyManager. Once new CDM is established CRBA will provide information to the Research Manager for entry into StudyManager.
- 202.2.1.4 Applicable Business and Occupation (B&O) state and city taxes will be incorporated into budget.
- 202.2.1.5 Inflation at a rate consistent with hospital inflation will be accommodated for budgets anticipated to span multiple years.
- 202.3 OSR will transmit the budget document to Investigator. Investigator must identify any omissions as this will be the basis of Children's negotiations with sponsor.
- 202.3.1 Final budget determination will reside with OSR in order to ensure that budget meets institutional requirements.

202.4 OSR contracts team will finalize the budget in negotiation with the Sponsor. Reference policy CTM-206.

202.5 Phased implementation of this policy:

202.5.1 The requirements of this policy will be implemented in a phased manner. OSR manager will direct whether a study is subject to these requirements.

202.6 Failure by either the investigator and/or research staff to adhere to this policy may result in suspension of clinical research activities for the investigator, and other disciplinary actions for the research staff.

#### **DEFINITIONS:**

##### **Charge Description Master (CDM) codes**

The Charge Description Master is a list of hospital charge codes for each service performed at Children's.

##### **Clinical Research Budget Analyst (CRBA)**

An OSR team member with extensive medical and research knowledge. The CRBA analyzes clinical research studies in order to make appropriate budgetary determinations. Some of the CRBA's responsibilities include: 1) categorizing protocol/study procedures as a standard of care or research care events, 2) determining time required for research staff activities, 3) capturing all associated start-up and maintenance costs and 4) identifying potential hidden costs.

##### **Lawson Activity Number**

Lawson activity numbers are used for research, special funds and projects. Activity numbers are required on both time cards and coding finance transactions. The Lawson Activity is a unique 12-digit number that represents the research or special funds designation, PI identifier, project identifier, contract level and budget period. Sponsored research at Children's always has a Lawson Activity Number with 41 as the first two digits.

##### **Research Patient Care Rate Agreement (RPCRA)**

The RPCRA is an agreement negotiated by Children's with its cognizant Division of Cost Allocation, HHS (DCA) office. It is a federally required adjustment to standard hospital charges, which is intended to reflect actual cost. It specifies how Children's is to charge Research Patient Care Costs to Research projects. Research Patient Care Costs, whether expressed as a rate or an amount, are computed in an amount consistent with the principles and procedures used by the Medicare program for determining the portion of Medicare reimbursement based on reasonable costs.

**Sponsor**


For purposes of this policy, a sponsor can be a company, institution, or organization that takes financial responsibility for (funds) a clinical trial.

**Study Manager**

A clinical trial management system (CTMS) that is designed to standardize and organize the process of implementing, conducting, and tracking clinical research studies. This Web-based software program creates budgets, organizes and tracks research patient visits, procedures and financial data. In addition, Study Manager creates reports to monitor research studies.

**Submitting Office:** Office of Sponsored Research

**Approved by:**

  
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Jennifer Dodson Date 3/9/07  
Director, Office of Sponsored  
Research

  
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Erik M. Lausund Date 3/9/07  
VP, Research Operations & Logistics