

SEATTLE CHILDREN'S HOSPITAL RESEARCH INSTITUTE
STANDARD OPERATING PROCEDURES / POLICIES

DEPARTMENT: Research Support Services
POLICY NUMBER: CTM-200
REPLACES: New
EFFECTIVE DATE: April 2, 2007
REVISION DATE: _____

POLICY TITLE: Research Patient Procedure Pricing

POLICY:

This policy establishes the clinical research revenue that will be charged to a study sponsor for clinical research procedures performed as part of any research protocol at Children's, Children's subcontractor or performance site.

PROCEDURE:

200.1 Federal Agency Research Pricing

200.1.1 The research price for clinical research procedures will be equal to the hospital charge amount listed in the hospital CDM on the date of service, multiplied by the Federal Research Patient Care Rate Agreement (RPCRA) in effect at that time (Table 1).

200.1.2 Regardless of the type of sponsor, the hospital charge to the research study budget for providing the clinical research services will be equal to the CDM multiplied by the RPCRA. Thus, for this federal study, the amount charged to the research study will be equal to the hospital cost of providing the service, as required by federal guidelines. (See Table 2 for an example calculation)

200.1.2.1 Exceptions may apply if the federal sponsor provides written instructions or policy requiring a different rate structure. The exception will need approval from the manager of the Office of Sponsored Research (OSR) prior to execution of the agreement.

200.2 Corporate Research Pricing

200.2.1 The research price charged to a corporate sponsor for clinical research procedures will be the hospital charge (CDM) multiplied by

the RPCRA and then increased to market rate using the Office of President, Seattle Children's Hospital Research Institute approved Clinical Pricing Markup in effect at that time.

200.2.2 Regardless of the type of sponsor, the hospital charge to the research study budget for providing the clinical research services will be equal to the CDM multiplied by the RPCRA. Thus, for this corporate study, the amount charged to the research study by the hospital cost for providing the service will be lower than the amount charged to the corporate sponsor. This will result in a residual balance left in the study budget at the completion of the protocol. (See Table 2 for an example calculation)

200.3 Foundation Research Pricing

200.3.1 Foundation Research Pricing (includes not-for-profit foundations, internal Children's awards, Children's bridge funds, Young Investigators Awards, Steering Committee Awards) will follow that of federal agency research pricing. (Refer to 200.1 above)

200.3.2 Regardless of the type of sponsor, the hospital charge to the research study budget for providing the clinical research services will be equal to the CDM multiplied by the RPCRA. Thus, for foundation and internal studies, the amount charged to the research study will be equal to the hospital cost of providing the service, as is typically required by not-for-profit foundations and gift funds. (See Table 2 for an example calculation)

200.4 Other Research Pricing

200.4.1 For all other research studies (any studies that are not any of the three categories above) the default pricing is that the corporate research pricing structure. Any deviation from the corporate research pricing must be pre-approved by the OSR manager prior to proposal of the contract.

200.5 Creating new CDM codes

200.5.1 All research pricing requires a CDM for each hospital service or research budget line item that will be performed for the study.

200.5.2 If an appropriate CDM does not currently exist, the CTBA will provide information about the service to hospital services. Hospital services will establish a new CDM in accordance with departmental or hospital policy. For clarification of the process to create a new CDM, contact the Director of Financial Planning and Reimbursement.

200.6 Facilities and Administration Costs (F&A)

- 200.6.1 All research study budgets must include the federally negotiated clinical F&A rate in effect for the duration of the clinical research study.
- 200.6.2 This F&A amount must be included in the calculated amount of budget payments from the protocol sponsor. In addition, this F&A amount will be charged against the study, to contribute to the research division for the costs incurred to provide the research and hospital infrastructure.
- 200.6.3 A waiver may be obtained to reduce the F&A rate applied to Federal, not-for-profit foundation, gift funded and internally funded studies. The waiver is signed by the Director of Research Finance or the Vice President, Research Operations and Logistics on behalf of the Office of President, Seattle Children's Hospital Research Institute prior to the execution of a grant or contract with the sponsor.
- 200.6.4 The Research Division will not waive F&A reimbursement for corporate sponsored studies.
- 200.6.5 The F&A dollar cost is calculated by multiplying the modified total direct costs (MTDC) by the clinical F&A rate. It should be noted that clinical research hospital charges are included in MTDC with two exceptions:
 - Federal guidelines require clinical research procedures to be excluded from the calculation of MTDC.
 - Certain not-for-profit foundations require clinical research procedures be excluded from the MTDC calculation. This is only allowable based on documented F&A policy from the foundation sponsor. In the absence of this policy guidance, MTDC is considered to include clinical research activities.

Table 1 – Pricing Matrix

	Hospital Charges GM Activity	Research Charges Sponsor	F&A rate Applied to Research Patient Care Charges?
Federal Projects	CDM * RPCRA	CDM * RPCRA	No. Research Patient Care not included in MTDC Base.
Corporate	CDM * RPCRA	CDM*RPCRA * (1+ Clinical Pricing Markup)	Yes, at then current Federal Clinical on campus F&A Rate.

Foundation	CDM * RPCRA	CDM * RPCRA	Yes, at maximally allowed rate, unless prohibited by Foundation policy.
Other	Follow Corporate Guidelines, unless waiver obtained from Manager, OSR.		

Table 2 – Example Calculation

For example purposes, let us suppose research patients incur a non-standard of care charge in radiology of \$100. Let us assume:

- the radiology RPCRA in effect at the time is 73%
- the F&A rate for clinical research is 41%
- The Clinical pricing markup margin is 50%
- Let us also assume that patient activities were not excluded from MTDC for Foundation X, but a waiver was obtained to reduce the F&A rate to 10%

Sponsor Type	Hospital Charge to Study (CDM) A	Research Price to Sponsor pre F&A B	F&A applied to patient activities C	Total Research Price to Sponsor D=B+C	Residual (Total Research price to sponsor less Hospital Charge less F&A charge) D-C-A
Federal	$\$100 \times 73\% = \73	$\$100 \times 73\% = \73	No	\$73	\$0
Corporate	$\$100 \times 73\% = \73	$\$100 \times 73\% \times (1 + 50\%) = \109.5	Yes, based on TDC of \$73 at a rate of 41% = \$29.9	$\$109.5 + 29.9 = \139.4	$\$139.4 - \$73 = \$66.4$ $\$66.4 - \$29.9 = \$36.5$
Foundation X	$\$100 \times 73\% = \73	$\$100 \times 73\% = \73	Yes, based on TDC of \$73, at a rate of 10% = \$7.3	$\$73 + \$7.3 = \$80.3$	$\$80.3 - \$73 = \$7.3$ $\$7.3 - \$7.3 = \$0$

200.7 Children's University Medical Group (CUMG) Physician Professional Fees

- 200.8 OSR will bring these principles to bear on finalization of budgets drafted in accordance with budget development process as described in CTM-202.
- 200.9 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.

Hospital Charge

This is the internal dollar amount that the hospital invoices for clinical research activities (e.g., radiology, lab work, etc.), and is equal to the amount that is recorded in the Children's Charge Description Master (CDM) in effect at the date of the event.

Professional Fees

The fees charged for physician services involved in the administration or interpretation of a patient procedure.

Research Patient Care Rate Agreement (RPCRA)

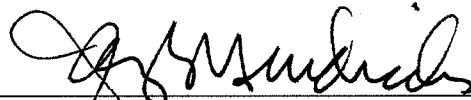
The RPCRA is an agreement negotiated by Children's with its cognizant Division of Cost Allocation, HHS (DCA) office. It is a federally required adjustment to standard hospital charges, which is intended to reflect actual cost. It specifies how Children's is to charge Research Patient Care Costs to Research 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.

Research Sponsor Price

This is the dollar amount charged to the sponsor of the research protocol, for clinical research activities (e.g., drug company, federal grant, intramural award etc.).

Submitting Office: President, Seattle Children's Hospital Research Institute

Approved by:


James Hendricks, PhD
President, Seattle Children's Hospital
Research Institute

3/15/07
Date