

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

DEPARTMENT: Research Support Services
POLICY NUMBER: CTM-203
REPLACES: New
EFFECTIVE DATE: April 2, 2007
REVISION DATE: _____

POLICY TITLE: Effecting Research Procedure Cost Transfer

POLICY:

It is Children's policy to make timely transfers from individual sponsored research activity accounts for research patient care events. Research accounts will be automatically debited on a monthly basis and a summary report will be generated and sent to Investigators for review.

PROCEDURE:

- 203.1 Every month Business Services will generate two copies of invoices (blue sheets) for all for charges generated for the preceding month.
 - 203.1.1 Blue sheets are sent to Office of Sponsored Research (OSR) and the noted guarantor (Investigator/Research Staff) registered on the account.
- 203.2 Every month the Research Billing Application will pull all research billing data from Invision and generate the Research Finance Lawson Report.
 - 203.2.1 Charges that are missing research billing information will automatically produce an error report.
 - 203.2.1.1 The CTBA will review the error report to resolve errors and coordinate with ORF for transfer of the appropriate charges, if indicated.
- 203.3 Within the Research Finance Lawson Report, the RPCRA is automatically applied to each procedure, according to policy CTM-010.

- 203.4 The Research Finance Lawson Report is uploaded to Lawson, by Research Finance staff, where the research accounts are debited as indicated in the report.
- 203.5 Every month the Research Finance Lawson Report is automatically sent to guarantor for review.
- 203.5.1 The guarantor will report any errors to the CTBA for follow up.
- 203.5.2 For error resolutions refer to Children's Policy CTM-208.
- 203.6 On a quarterly basis and at study completion, the RCA will perform a funds transfer confirmation review (refer to Policy CTM-207).

DEFINITIONS:

Blue Sheet

The billing invoice showing research care events delivered and stating the associated costs.

Business Services

The Business Services office at Children's manages the billing and collecting for patient clinical care as well as research accounts.

Clinical Trial Budget Analyst (CTBA)

An OSR team member with extensive medical and research knowledge. The CTBA analyzes clinical research studies in order to make appropriate budgetary determinations. Some of the CTBA'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.

Guarantor

An individual who assumes fiscal responsibility for procedures performed on a specific patient. The Investigator or study team member is listed as guarantor for research patient accounts and the parent/guardian is listed as the guarantor for clinical, standard of care accounts.

Lawson System

Lawson is a Web-based business software application that assists with the management of financial and capital resources, personnel-related information and materials distribution and inventory.

Research Compliance Auditor (RCA)

An individual that is accountable for audit, quality assurance, and error resolution in research-related patient care billing matters and systems. The RCA monitors

and evaluates the effectiveness of Clinical Research Patient Care Charging Systems and conducts regular auditing and monitoring activities of research billing activities at Children's. The RCA has the authority to review all documents and other information that are relevant to research billing compliance activities.

Research Finance Lawson Report

A report developed from research billing (blue sheet) data extracted from Invision. The RPCRA rates are calculated by formulas within the report, resulting in the adjusted research patient care fees to be charged. Adjusted charges will be uploaded to Lawson and the research accounts debited accordingly.

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.

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

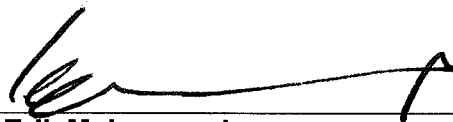
Approved by:



Jennifer Dodson
Director, Office of Sponsored
Research

Date

3/9/07



Erik M. Lausund
VP, Research Operations & Logistics

Date

3/9/07