

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

DEPARTMENT: Research Support Services
POLICY NUMBER: CTM-208
REPLACES: New
EFFECTIVE DATE: April 2, 2007
REVISION DATE: _____

POLICY TITLE: Clinical Research Patient Care Cost Charge Direction Error Resolution

POLICY:

Children's conducts clinical trials in keeping with the provisions of compliant billing practices. Auditing/Monitoring or other activity may uncover errors in charge direction. It is Children's policy and practice to rectify any such errors immediately upon identification.

PROCEDURE:

208.1 Scheduled Auditing Error Resolution

- 208.1.1 RCA identified research patient billing error(s) are reported to Children's Business Services, using electronic Clinical Research Error Resolution Form.
 - 208.1.1.1 Overcharged and noncompliant charges: Provide business services patient name, date of service, quantity, account numbers and CDM codes for the identified error charges.
 - 208.1.1.2 Missing charges: if no charge can be found in INVISION for the research procedure provide service date, patient name, quantity, charge department, guarantor and CDM code/procedure type.
 - 208.1.1.3 All identified errors are noted in StudyManager Auditing Report next to the research procedure that has the associated error. This will be a marker for verification that the error has been corrected.
- 208.1.2 Semi-annually, the RCA will provide a comprehensive report to the Director OIA and the Office of the President, Seattle Children's Hospital Research Institute summarizing the error identified.
 - 208.1.2.1 The report shall include a categorization of errors, identifying error causes to the extent possible.

- 208.1.2.2 The report recipients will evaluate the report and, to the extent indicated, instruct system or process changes or staff disciplinary action to reduce or eliminate recurrences.
- 208.1.3 Within 3 business days of notifying Business Services of the error(s), RCA will verify account has been corrected in INVISION.
 - 208.1.3.1 If correction has not occurred, review with Business Services leadership.
 - 208.1.3.2 RCA will place confirmatory note in StudyManager Auditing Report that the error has been corrected by Business Services.
- 208.2 Guarantor reviews blue sheets and identifies errors.
 - 208.2.1 Guarantor contacts CTBA to discuss the identified error.
 - 208.2.2 CTBA notifies Business Services of the identified error using the electronic Research Charge Error Resolution Form.
 - 208.2.3 Business Services will reflect the charge changes on the following month's blue sheets.
 - 208.2.4 Review and correction of blue sheet charges must occur within 30 days of blue sheet issuance.

DEFINITIONS:

Blue Sheet

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

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.

Research Care Events (also known as Research Patient Procedures)

Items and services (routine and ancillary) provided for research purposes by Children's to individuals participating in clinical research. The costs of these services are typically assigned to a specific research study. Such items or

services may be diagnostic, therapeutic, rehabilitative, medical, psychiatric, or any other related professional health services.

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 Patient Care Costs

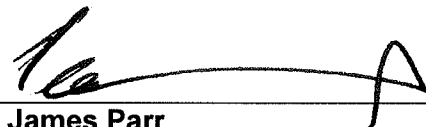
Refers to Research Care Event

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. The 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 Research Finance

Approved by:



James Parr
Director, Office of Research Finance

3/19/07
Date



Erik Lausund
VP, Research Operations and
Logistics

3/19/07
Date