

SEATTLE CHILDREN'S HOSPITAL RESEARCH INSTITUTE

STANDARD OPERATING PROCEDURES / POLICIES

DEPARTMENT: Research Support Services

POLICY NUMBER: CTM-207

REPLACES: New

EFFECTIVE DATE: April 2, 2007

REVISION DATE: _____

POLICY TITLE: Auditing Research Patient Care Cost Compliance

POLICY:

Children's Research Division maintains processes and procedures that monitor the effectiveness of research patient procedure charge direction and effectively identifies charge errors in a timely manner. The process monitors the activity of all Clinical Trials conducted at Children's. The process monitors Clinical Trials on a regular schedule as outlined below. Investigators and research staff are required to cooperate fully in any audit inquiries.

PROCEDURE:

207.1 Setting Monitoring Plan

- 207.1.1 Research Compliance Auditor (RCA) is notified by Office of Sponsored Research (OSR) of new clinical trial. RCA will receive copy of contract, budget, and estimated duration.
- 207.1.2 RCA sets a monitoring plan for this project.
- 207.1.3 At a minimum, 85 percent of all open studies within StudyManager will be audited on a quarterly basis, until the last patient completes protocol.
- 207.1.4 Investigators will be notified regarding their studies being audited. Investigators or staff may be contacted during the audit process.
 - 207.1.4.1 Investigators and research staff are required to cooperate fully in any audit inquiries and time incurred should be charged to the study being audited, except in instances where the study budget has closed. Further questions regarding time charging should be directed to the Office of Sponsored Research.

207.2 Quarterly Audit Procedure

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- 207.2.1 RCA generates a report showing all procedures that have been completed within the auditing time frame. StudyManager is used to generate the auditing data set.
- 207.2.2 RCA obtains corresponding INVISION data, "Research Patient Procedure Billing Report". The "Research Patient Procedure Billing Report" delineates the charges that were directed to patient's research account(s).
 - 207.2.2.1 If no INVISION report is generated then a manual review is conducted by searching INVISION for individual (patient, research) accounts to determine the research procedures that have been charged.
- 207.2.3 RCA will identify discrepancies between the two data sources: StudyManager and INVISION.
- 207.2.4 RCA will review identified discrepancies with study staff to rule out possible inaccurate recordings in either system.

207.3 Error Resolution

- 207.3.1 If no errors are found, RCA proceeds to complete audit report (see 207.4).
- 207.3.2 For error resolution fix, refer to Policy CTM-208.

207.4 Audit Reports

- 207.4.1 Quarterly Reporting of Compliance Audit:
 - 207.4.1.1 RCA reports findings of discrepancies to the Investigator, Office of Sponsored Research, Research Finance, Centers Directors Advisory Committee, Director of Office of Institutional Assurance (OIA) and Office of President, Seattle Children's Hospital Research Institute.
 - 207.4.1.2 If no discrepancies at quarterly monitor RCA sends "No Discrepancies" report to the Investigator, Office of Sponsored Research, Research Finance, Centers Directors Advisory Committee, and Office of President, Seattle Children's Hospital Research Institute.
 - 207.4.1.3 RCA shall retain copies of reports and review documentation for a period of seven (7) years after conclusion of the review or seven (7) years after completion of the federally-sponsored project, whichever is longer.

Study Completion

207.5 Funds Transfer Confirmation Review

- 207.5.1 This review is conducted when all research care event activity is completed.
- 207.5.2 All study Funds Transfer shall be audited for completeness and accuracy.

- 207.5.3 RCA obtains Funds Transfer data from the Lawson System (ERP), Crystal reporting form AC295. The Office of Research Finance is responsible for form AC295 completeness.
- 207.5.4 RCA will assess:
 - 207.5.4.1 RCA will identify and assess any differences between the ORF Funds Transfer Report and StudyManager Report of completed research procedure to ensure that appropriate funds have been transferred.
 - 207.5.4.2 RCA will confirm whether appropriate RPCRA rate was applied, using the Service Department identification contained within the CDM code and the cross reference tables.
- 207.5.5 Completed Studies Debited Costs Audit Report
 - 207.5.5.1 If no errors are found, RCA prepares final report for distribution to the Investigator, Office of Sponsored Research, Research Finance, Centers Directors Advisory Committee, and Office of President, Seattle Children's Hospital Research Institute.
 - 207.5.5.2 If the RCA identifies errors, s/he will provide the information for corrective action, as described in CTM-208.
 - 207.5.5.2.1 Any errors identified are reported to the Director, Office of Research Finance for corrective action. Documentation of corrective action performed is provided to RCA report within 10 working days.
 - 207.5.5.3 Copies of report and corrective action documentation to the Investigator, Office of Sponsored Research, Research Finance, Centers Directors Advisory Committee, Director of Office of Institutional Assurance (OIA) and Office of President, Seattle Children's Hospital Research Institute.
 - 207.5.5.4 RCA performs an analysis to determine the cause of errors. RCA develops corrective action plan to minimize risk of recurrence. Corrective action plan shall be filed with Director OIA and Office of President, Seattle Children's Hospital Research Institute.
 - 207.5.5.5 RCA shall retain copies of reports and review documentation for a period of seven (7) years after conclusion of the review or seven (7) years after completion of the federally-sponsored project, whichever is longer.
- 207.5.6 Completed Studies Compliance Audit Report
 - 207.5.6.1 RCA will provide summary report to the Investigator, Office of Sponsored Research, Research Finance, Centers Directors Advisory Committee, Director of Office of Institutional Assurance (OIA) and Office of President, Seattle Children's Hospital Research Institute.
 - 207.5.6.2 Summary report shall include:

- 207.5.6.2.1 Summary of discrepancies from monitoring
 - 207.5.6.2.2 Summary of errors identified
 - 207.5.6.2.3 Summary of corrective action plans
 - 207.5.6.3 Identification of persistent sources of discrepancies or errors.
- 207.6 Semi-annually, the RCA will provide a comprehensive report to Director of OIA and Office of President, Seattle Children's Hospital Research Institute summarizing the errors identified.
- 207.6.1 The report shall include a categorization of errors, identifying error causes to the extent possible.
 - 207.6.2 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.
- 207.7 Concerns regarding this policy or performance under this policy should be filed with the Director OIA. For purposes of this policy, the VP, Research Operations and Logistics is acting in the Director OIA capacity.
- 207.8 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:

Clinical Research (also called Clinical Trial or Study throughout this policy)

NIH defines clinical research as research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. This area of research includes mechanisms of human disease, therapeutic interventions, clinical trials and development of new technologies. Clinical research can also include epidemiologic and behavioral studies or outcomes research and health services research.

INVISION

INVISION is Children's electronic Master Patient Index, Patient Registration system and Patient Accounting system.

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 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.

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

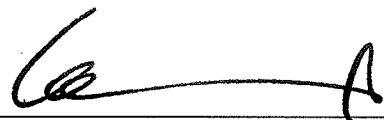
A clinical trial management system (CTMS) that is designed to standardize and organize the process of implementing, conducting, and tracking clinical research studies. This Web-based software program creates budgets, organizes and tracks research patient visits, procedures and financial data. In addition,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

Submitting Office: Office of Research Finance

Approved by:



James Parr Date
Director, Office of Research Finance



Erik Lausund Date
VP, Research Operations and
Logistics