

**SEATTLE CHILDREN'S RESEARCH INSTITUTE
OPERATING POLICIES / PROCEDURES**

DEPARTMENT: Research Support Services
POLICY NUMBER: CTM-201
REPLACES: CTM-201 v4-02-07
EFFECTIVE DATE: 8/17/09
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TITLE: Financial Responsibility Analysis

SUMMARY:

This policy provides clarification on the responsibility the Office of Sponsored Research (OSR) has in assuring the appropriate identification and classification of protocol/study events in Clinical Research as part of the budget development process.

POLICY/PROCEDURE:

- 201.1 The Investigator/research staff will provide the Clinical Research Budget Analyst (CRBA) in OSR with an electronic copy of the final protocol or the grant award. Note that the **final version** of the protocol or the grant award is necessary for financial responsibility analysis.
- 201.2 The CRBA will review the protocol or grant award and create a FRA.
 - 201.2.1 The protocol and schedule of events will be reviewed to create a study matrix of all patient care items and services.
 - 201.2.2 Patient care items and services will be analyzed according to payor guidelines and financial responsibility for each such item or service will be assigned either to the patient/family or third party payor, or to the sponsor or internal research account.
 - 201.2.3 Refer to Policy CTM-202 for identification of staff time projections, startup and maintenance costs and hidden costs determination.
- 201.3 The draft FRA is sent for review and approval by the Investigator.
 - 201.3.1 An Investigator may request a change in financial responsibility for a care event.

- 201.3.1.1 Approval of the Investigator's request will follow this rule:
 - 201.3.1.1.1 If consensus between the Investigator and the CRBA is reached, then the change can be made.
 - 201.3.1.1.2 If consensus between the Investigator and the CRBA cannot be reached, then the Medical Director will be the final arbiter.
- 201.3.2 Documentation of review and approval by the Investigator will be obtained by OSR. Approval may be in the form of a hard copy signature or approval e-mail from the investigator.
- 201.3.3 Copy of the final FRA will be sent to the investigator and primary study contact and the original maintained by OSR.
- 201.4 The CRBA will ensure that protocol/study events assessed to be the responsibility of the research account are accordingly flagged in StudyManager based on the final FRA.
- 201.5 When the study begins, all study events will be billed to either the patient/family/insurance or the Study Code established for the project as stipulated in the final and approved FRA. Further, once the FRA is complete and approved by the CRBA and PI, it cannot be changed unless and until:
 - 201.5.1 OSR is able to document that the proposed changes are allowable under the award governing the project, or the award is modified so as to allow the changes; and
 - 201.5.2 The IRB protocol and/or consent form are modified to account for the changes.
- 201.6 The process for modification of an IRB application and corresponding FRA shall be as follows:
 - 201.6.1 The investigator will request approval of a modification using the IRB Modification Request Form. As part of said form, the Investigator will answer whether any of the changes will result in the addition or elimination of billable events. If so, the Investigator will attest to ensuring that both the FRA and Study Manager data will be updated for the study.
 - 201.6.2 Upon receipt of IRB Modification Request Forms that include an indication that the requested changes will impact billable events in this

way, the HSPP staff will route a copy of said Form to the CRBAs so they have notice of such pending modifications.

- 201.6.3 In addition, HSPP will notify the CRBA upon IRB approval of the modification.
- 201.7 Investigators wanting to update their FRAs should also contact the CRBA directly. The CRBA will coordinate with the OSR Contracts Group or appropriate Sponsored Project Officer to review the award and, if necessary, secure any sponsor approvals needed for the changes.
- 201.8 Once the conditions described in §201.6 and §201.7 are met, the CRBA will create an updated FRA following the steps described above. Upon PI and CRBA approval of the updated FRA, the CRBA will update the study record in Study Manager.
- 201.9 For budget finalization, including the consideration of non-patient care costs, refer to Policy CTM-202 Clinical Trial Budget Creation in Study Manager.
- 201.10 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:

Financial Responsibility Analysis (FRA)

The process of identifying whether responsibility for payment for a protocol/study event is the responsibility of the patient (or patient's family or insurer) or the responsibility of the party funding the research such event is associated with.

and/or

Spreadsheet documenting the assignment of financial responsibility for study events resulting from the analysis (see Exhibit A).

Harmonization

Harmonization is a process for ensuring that the four key administrative components describing a clinical study (IRB application, consent form, FRA, and award document) are consistent in their identification of the party responsible for the payment of the costs associated with incorporated clinical services and events. However, because these documents serve different audiences and for different purposes, follow different structures and are written in very different styles, the expectation of an exact match in all content and language is unreasonable. Therefore, the guiding principle regarding harmonization is that the individual documents should not be in conflict with regard to the assignment of responsibility for any given patient care cost.

Hospital Services

Service areas within Children's that perform procedures for the diagnosis and treatment of patients. These services are utilized for clinical as well as research activities and include departments such as radiology, laboratory and pharmacy.

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.

StudyManager

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, StudyManager creates reports to monitor research studies.

Submitting Office: Research Support Services

Approved by:

\\s\ John M. Streck, Chief, Research Operations, 8/17/09

\\s\ Erik M. Lausund, Vice President, Research Operations 8/17/09