

**SEATTLE CHILDREN'S HOSPITAL RESEARCH INSTITUTE**

**STANDARD OPERATING PROCEDURES / POLICIES**

**DEPARTMENT:** Research Support Services  
**POLICY NUMBER:** CTM-206  
**REPLACES:** CTM-206 (April 2, 2007)  
**EFFECTIVE DATE:** March 16, 2009  
**REVISION DATE:** March 13, 2009

**POLICY TITLE:** Clinical Trials Contract Negotiation

**POLICY:**

Children's requires all clinical trials to be carefully reviewed, negotiated and executed (signed) by authorized staff in the Office of Sponsored Research. These staff and the CRBA are responsible for budget development, review and finalization of contract terms and conditions. PI input, through the OSR contracts staff, is expected and necessary, to ensure coordinated concurrence and commitment to the terms of science, budget, scope of work expectations, timing, risk management and intellectual property issues.

Work cannot start on a clinical trial until the contract agreement has been fully executed by the sponsor and Children's.

**PROCEDURE:**

- 206.1 Submission of a Clinical Trail Request Form (CTRF) to the OSR contracts staff ([ResContracts@seattlechildrens.org](mailto:ResContracts@seattlechildrens.org)) is the first step in the process for establishing a clinical trial agreement. The submitted CTRF is used to drive the other steps in the process.
- 206.2 The CRBA performs an analysis of the protocol and determines the pricing for the project through input in StudyManager. The completed project budget is signed by the CRBA and the PI to confirm their approval of the identified costs. The budget is given to the OSR contracts staff members who will use the information to inform their negotiations with the sponsor.
- 206.3 The OSR contracts staff contacts the sponsor to develop an agreement to govern the trial. Contracts staff will review the draft contract for issues of budget and funding, and consistency of the contract language with applicable regulations and Children's policies.
- 206.3.1 The following are issues of concern related to the budget:

- 206.3.1.1 Timing of incurred expenses versus expected revenue, and the proper compensation for fixed versus variable costs.
  - 206.3.1.2 Ensuring the budget covers the minimum costs estimated to conduct the trial, including patient care events, professional fees, committed time of PI and research staff, appropriate inflation, indirect costs and B&O taxes (refer to Policy CTM-200 and CTM-202).
  - 206.3.1.3 If negotiations with Federal Agency or Foundation sponsor do not meet the minimum budgetary requirements, special approval may be secured from the Chief of Research Operations or Vice President, Research, for cost sharing.
  - 206.3.1.4 Children's will not execute a CTA with any corporate sponsor that fails to meet the minimum standards set for budgets, including, but not limited to, full Federal F&A and OVPR corporate research margin (refer to Policy CTM-200).
- 206.3.2 OSR is charged with protecting the interests of the PI, the Institution, and research participants. Institutional standards regarding clinical trial contract language are outlined in the OSR Clinical Trials Agreement Handbook, and include:
- 206.3.2.2 Indemnification, insurance requirements and governing law. If the contracts specialist needs assistance in determining acceptable level of commitment in these areas they must first consult with the OSR Contracts Supervisor. If issues continue to be unresolved, the Contracts Supervisor will consult with the Chief of Research Operations and/or Vice President, Research. Issues still unresolved will be referred to Risk Management and/or Legal Department at Children's.
  - 206.3.2.3 Intellectual property issues including confidentiality, intellectual property with respect to inventions, publication rights and general terminology. If the contracts specialist needs assistance in determining acceptable level of commitment in these areas they must first consult with the OSR Contracts Supervisor. If issues continue to be unresolved, the Contracts Supervisor will consult with the Chief of Research Operations and/or Vice President, Research. Issues still unresolved will be referred to Children's Intellectual Property core for determination.

- 206.4 Prior to final contract execution, the project must go through institutional sign-off as described in policy OSR-010.
- 206.5 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 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. 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.

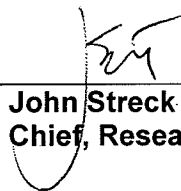
**Sponsor**

For purposes of this policy, the sponsor is the entity -- company, institution, or organization -- that provides the funding for a clinical trial.

**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: Office of Sponsored Research**

Approved by:  3/16/09  
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**John Streck** **Date**  
**Chief, Research Operations**