

# SEATTLE CHILDREN'S HOSPITAL RESEARCH INSTITUTE

## CLINICAL TRIAL MANAGEMENT (CTM) STANDARD OPERATING PROCEDURES / POLICIES

<b>DEPARTMENT:</b>	Research Support Services
<b>POLICY NUMBER:</b>	CTM-100
<b>REPLACES:</b>	April 2, 2007
<b>EFFECTIVE DATE:</b>	April 2, 2007
<b>REVISION DATE:</b>	June 13 <sup>th</sup> , 2007

**POLICY TITLE:** StudyManager Utilization and Compliance

### **POLICY:**

Children's is committed to compliance in Clinical Research and Research Patient Care Billing. To maximize Children's compliance efforts, StudyManager, a Clinical Trial Management System has been initiated at Children's to track research participant activity and create billing audit reports.

The aim of this policy is to clarify the expectations of investigators and research staff in using StudyManager in order to achieve Children's goal of research billing compliance. It is each investigator and research staff member's responsibility to comply with this policy.

All clinical research studies that involve billable research care events or a mixture of research care events and standard of care events that generate hospital charges are required to utilize StudyManager. StudyManager will be used for budget building, patient enrollment and study visit tracking. Utilization of StudyManager is required of all new Clinical Research Studies at Children's that meet the above criteria.

The Office of Clinical Research is responsible for the operation of StudyManager Software and adherence to StudyManager related policies.

### **PROCEDURE:**

- 100.1 All clinical research studies that involve billable research care events or a mixture of billable research care events and standard of care events are required to utilize StudyManager.
- 100.2 Patient enrollment, status and documentation of completed study procedures in StudyManager should occur immediately during the research participant visit. If this is not possible, data must be entered into StudyManager within two business days.
  - 100.2.1 For visit procedures completed on multiple dates, StudyManager data must be entered within two business days of procedure completion.
  - 100.2.2 The primary contact for the study is responsible for updating StudyManager.

- 100.2.2.1 The research team member administering or overseeing the study procedures should track those procedures in StudyManager. However, the primary contact for the study remains ultimately responsible for this data.
- 100.2.2.2 When on leave, it is expected that staff will arrange coverage for StudyManager data entry. However, the primary contact for the study remains ultimately responsible for this data.
- 100.3 Children's has a guideline for StudyManager non-compliance committed by investigators or research staff.
  - 100.3.1 The guideline for StudyManager Non-Compliance is shown in Appendix 1.
  - 100.3.2 The guideline illustrates the stages of disciplinary action; however each instance of non-compliance will be evaluated on a case by case basis.
- 100.4 Exemptions to this policy will require signoff by the Director of the Office of Clinical Research and the Director of the Office of Sponsored Research.
- 100.5 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**

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, development of new technologies. Clinical research can also include epidemiologic and behavioral studies or outcomes research and health services research.

##### **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.

##### **Standard of Care Events**

Items and services (routine and ancillary) conventionally furnished in the treatment of patients by providers of patient care under the supervision of the physician or other responsible health professional and billed to the patient or a third party payor. Such items or services may be diagnostic, therapeutic, rehabilitative, medical, psychiatric, or any other related professional health services.



# Appendix 1 –Guideline for StudyManager Non-Compliance

