

SEATTLE CHILDREN'S HOSPITAL RESEARCH INSTITUTE

OPERATING POLICIES / PROCEDURES

DEPARTMENT: Research Support Services

POLICY NUMBER: CTM-313

REPLACES: New

EFFECTIVE DATE: April 2, 2007

REVISION DATE: _____

POLICY TITLE: **Clinical Research Study Start Up**

POLICY:

Children's is committed to implementing clinical research studies in an efficient, organized and compliant manner. The Office of the President, Seattle Children's Hospital Research Institute will maintain processes and procedures that support study start up. This policy outlines the process for initiating clinical research studies at Children's.

PROCEDURE:

313.1 It is the responsibility of the Principal Investigator to ensure that the following are in place prior to initiating a clinical research study at Children's:

1. Final Institutional Review Board (IRB) approval.
2. Final Scientific Advisory Committee (SAC) approval (if applicable).
3. Executed contract or grant, when applicable for sponsored research.
4. A designated research staff member responsible for daily administration and implementation of the study. Examples include a Clinical Research Associate (CRA), Research Coordinator (RC), or Research Nurse. All study team members must have completed Human Subjects Protection Training.
5. Lawson activity number.
6. Notification to and endorsement from the Hospital service area being utilized.
7. All study supplies, documents, and equipment available.
8. Completed Protocol Implementation Meeting (PIM).
9. Verification of study entry into StudyManager by the Office of Sponsored Research (OSR).

313.1.1 A worksheet is provided for reference in Appendix 1.

- 313.1.2 The above list is not all inclusive. There may be additional requirements for your study.
- 313.2 Final Institutional Review Board (IRB) approval
 - 313.2.1 Final Children’s IRB approval must be received before any human subjects/clinical research may begin. This includes, but is not necessarily limited to, advertising/recruitment and consenting as well as participant visits, medical chart reviews, and any research related to existing tissue/specimens.
 - 313.2.1.1 All Children’s IRB contingencies for approval must be met such that you receive written notice of final IRB approval.
- 313.3 Final Scientific Advisory Committee (SAC) approval (if applicable)
 - 313.3.1 Final SAC approval must be received before any research participant visits or medical chart review related to clinical study activities may begin.
- 313.4 Executed contract or grant
 - 313.4.1 When applicable for sponsored research, a final executed contract or grant must be received before any research participant visits or medical chart review related to clinical study activities may begin.
 - 313.4.2 All clinical research studies conducted at Children’s must have provisions for funding to cover study related activities.
- 313.5 Designated research staff member
 - 313.5.1 A qualified research staff member must be designated to work on the study before any research participant visits or medical chart review related to clinical study activities may begin.
 - 313.5.2 Each member of the study team must have completed Human Subjects Protections Training before being involved in any clinical study activities.
 - 313.5.3 Refer to policy CTM-300 Research Staff Qualifications for guidance.
- 313.6 Lawson activity number
 - 313.6.1 A study-specific Lawson activity number must be available before any research participant visits or medical chart review related to clinical study activities may begin.

313.7 Hospital Services

313.7.1 Prior to utilizing Hospital Services for clinical research activities the Investigator/Research Staff must coordinate services with the hospital service. A table of research contacts in hospital service areas is attached for reference in Appendix 2.

313.7.1.1 It is the responsibility of the Investigator/Research Staff to notify hospital services of study status and expected start date of study activities.

313.7.1.2 The Investigator/research team must address the resource, training and documentation needs for the service area.

313.7.2 Paper research requisitions are required to obtain hospital services resources.

313.7.2.1 Research participants must be registered as research patients in the Hospital system (See policy CTM-312).

313.7.2.2 The appropriate research label must be placed on the hospital requisition.

313.8 All study supplies, documents, and equipment are available

313.8.1 All study supplies, documents, and equipment must be available before any research participant visits related to clinical study activities may begin.

313.9 Protocol Implementation Meeting (PIM)

313.9.1 It is the responsibility of the Principal Investigator to conduct a PIM prior to initiating a clinical research study at Children's.

313.9.2 At the PIM, all elements listed in section 313.1 of this policy should be reviewed for completeness and accuracy.

313.9.3 PIM attendees should include relevant members of the research team (PI, Research Nurse, etc.), representatives from hospital service areas being utilized (IDS, clinical lab, radiology, etc.), primary PCRC nurse (if utilizing the PCRC), and any other individuals integral to the study.

313.9.4 A PIM worksheet is attached in Appendix 3 for reference.

313.10 Verification of study entry into StudyManager by the Office of Sponsored Research (OSR)

- 313.10.1 In accordance with policy CTM-100, Utilization of StudyManager, all clinical research studies that involve research care events or a mixture of research care events and standard of care events that generate hospital charges will be required to utilize Study.
- 313.10.2 Contact the Office of Clinical Research if you need StudyManager access or training.
- 313.11 Exceptions to the requirements of this policy may include chart review, epidemiological and emergency use protocols.
- 313.11.1 Contact the HSPP or the Office of Clinical Research (OCR) for guidance if you are unsure if you qualify for an exception from this policy.
- 313.12 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:

Budget Number

Refers to Lawson Activity Number (see below).

Clinical Research Associate (CRA)

CRAs assist the research team with the organization, implementation, and completion of research studies. They ensure that the research team conducts the study according to Good Clinical Practices; ensure that all applicable regulatory requirements are being met; track adverse events; assist the investigator with and review accuracy of site records (IRB, regulatory binder, source documents & case report forms); and perform other clinical study related activities. Unless specifically certified to do so, CRAs do not perform direct care activities.

Clinical Research Coordinator (RC)

An RC is a nurse or other licensed health care professional who works under the direction of a principal investigator (PI). This individual, whose research activities are conducted under Good Clinical Practice regulations, is the organizer of the day-to-day conduct of study activities with the research subject. These activities may include, but are not limited to; screening, recruitment consenting and scheduling of potential research subjects, and completing and maintaining the quality of research documents (source documents, case report forms). In addition, depending on their licensure an RC may perform direct care activities such as vital signs, blood draws, and administering medications.

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

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.

Lawson Activity Number

Lawson activity numbers are used for research, special funds and projects. Activity numbers are required on both time cards and coding finance transactions. The Lawson Activity is a unique 12-digit number that represents the research or special funds designation, PI identifier, project identifier, contract level and budget period. Sponsored research at Children's always has a Lawson Activity Number with 41 as the first two digits.

Pediatric Clinical Research Center (PCRC)

An NIH funded facility located at Children's that provides space, resources and support for the implementation and conduct of clinical research studies.

Protocol Implementation Meeting (PIM)

A meeting organized and conducted by the Investigator and/or the RC/CRA. The purpose of the PIM is to educate key personnel concerning the implementation and conduct of a clinical research study, particularly with regards to the roles and responsibilities of each individual participating in the study. At the PIM, the study is discussed in detail, logistics of protocol execution defined, barriers to smooth implementation identified, issues identified and plans for resolving discussed. Meeting participants are anyone involved in any aspect of the conduct of the research study.

Research Nurse

A licensed registered nurse (RN) works under the direction of a principal investigator (PI). This individual, whose research activities are conducted under Good Clinical Practice regulations, is the organizer of the day-to-day conduct of study activities with the research subject. These activities may include, but are not limited to: screening, recruitment consenting and scheduling of potential research subjects, and completing and maintaining the quality of research documents (source documents, case report forms). In addition a research nurse performs direct care activities such as vital signs, blood draws and administering medications. Research nurses are members of the Washington State Nurses Association (WSNA).

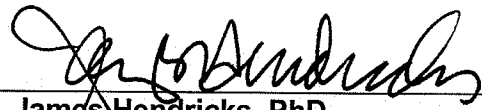
Research Staff (Research Team Members)

Individuals who contribute in a substantive way to the research project. These may be team members who are responsible for the scientific development or conduct of a research study, members who interact directly with the participants or

their individually identifiable private health information, e.g., obtain consent or assent, conduct research visits, administer research surveys, questionnaires, or review medical records for research purposes. Team members may include but are not limited to: co-investigator(s), post-doctoral fellow(s), graduate student(s), research technician(s), research assistant(s), research coordinator(s) and research technologist(s).

Submitting Office: **President, Seattle Children's Hospital Research Institute**

Approved by:



James Hendricks, PhD
President, Seattle Children's Hospital
Research Institute

Date

4/13/07

Appendix 1 - Minimum requirements for study start up at Children's

1. This checklist is provided as a tool to assess that all applicable items are in place prior to initiating a clinical research study at Children's.
2. Be aware that your study may have some additional requirements before any research participant related activities can begin.

- | | |
|---|--------------------------|
| <input type="checkbox"/> FINAL IRB approval | Date Approved: _____ |
| <input type="checkbox"/> Final Scientific Advisory Committee (SAC) approval (if applicable) | Date Approved: _____ |
| <input type="checkbox"/> Executed contract or grant | Date Executed: _____ |
| <input type="checkbox"/> A designated RC or CRA | RC/CRA Name: _____ |
| <input type="checkbox"/> Verification that all study team members have completed Human Subjects Protection Training | |
| <input type="checkbox"/> Lawson activity number | Lawson Activity #: _____ |
| <input type="checkbox"/> Notification of Hospital Services being utilized | |
| <input type="checkbox"/> All study supplies, documents, and equipment are available | |
| <input type="checkbox"/> Protocol Implementation Meeting (PIM) | Date of Meeting: _____ |
| <input type="checkbox"/> Verification of study entry into StudyManager by the Office of Sponsored Research (OSR) | |

Appendix 2 - Research Contacts for commonly used hospital service areas at Children's

Hospital Service	Research Contact
Cardiology	Jake Hawksworth / Mark Lewin
Clinical Laboratory Services	David Stanley
CUMG	Joy Novack
EEG	Michelle Gregory / Patti Hovik
ER	Julie Brown
HSPB	Tom Conquergood
IICU	Lauren Thorngate
Investigational Drug Services	Morty Cohen (Lara Winter for HemOnc)
Medical Unit	Georganne Haglund
Odessa Brown Children's Clinic	Paula Holmes / Jaime Hamamura
Office of Biostatistical Services	Kristy Seidel
Office of Business Services	Suzanne Vanderwerff
Office of Clinical Research	Clinton Vickers
Office of Research Finance	Jo Bloch
Office of Sponsored Research	Jennie Dodson
Operating Room and Anesthesia	Cheryl Tada
OR/PACU/Anesthesiology	Dan Moore
Pediatric Clinical Research Center	Sharon Schneider
PICU	Debra Ann Ridling
Pulmonary Function Tests	David Stamey
Radiology	Pat Smoll
Research Specimen Processing Lab	Josh Reynolds
Respiratory Therapy	John Salyer
Surgical unit	Lisa Peters

Appendix 3 - PIM checklist

PROTOCOL IMPLEMENTATION MEETING (PIM)

DATE _____

PROTOCOL TITLE: _____

I. Overview of the Study	Comments/Follow up (Include individual to complete and by what date)
<input type="checkbox"/> Presentation of protocol (presented by the Investigator) <ul style="list-style-type: none"> • Most current copy of the protocol • Final IRB approval? • When is PI projecting that study will start? • Review recruitment and consenting process. 	
II. Roles & Responsibilities	
<input type="checkbox"/> Review responsibilities of each research team member, and any ancillary department involvement (Lab, pharmacy, radiology, CRC, etc); required to perform protocol activities. <ul style="list-style-type: none"> • All staff working on the protocol must be Children's employees. If they are not please see note below under "other" <input type="checkbox"/> Walk through the study visits.	
<input type="checkbox"/> Assess what, if any, new skills are required by research staff <input type="checkbox"/> Training completed or scheduled?	
<input type="checkbox"/> Review procedure for obtaining and processing specimens (if applicable). Including: <ul style="list-style-type: none"> • discussion of supplies required (blood drawing supplies, cryovials, etc) • blood to be drawn from line, vein, etc. • Review maximum blood volumes • Are some samples optional? • Review shipping procedures • If labs to be done at Children's review process for obtaining lab requisition 	
<input type="checkbox"/> Evaluate what equipment/supplies are necessary to perform the study. <input type="checkbox"/> Is storage needed for supplies, if so arrange where	
III. Review of forms	Comments/Notes
Forms Completed? <input type="checkbox"/> Protocol Fact Sheets/Protocol Summaries Complete <input type="checkbox"/> Study schema/calendars <input type="checkbox"/> Instruction sheets (Examples are study drug administration; preparation and shipping of specimens to central lab; performing a study specific procedure. <input type="checkbox"/> Case report forms/roadmaps <input type="checkbox"/> Pre-printed orders <input type="checkbox"/> Eligibility checklist <input type="checkbox"/> Review regulatory filing system (Consent, HIPAA, etc.)	

IV. Registration	
<input type="checkbox"/> Registration needs <ul style="list-style-type: none"> • Are patients having research procedures at Children's that are to be billed to the study? If yes, the patient will need to be registered for research. • If patient is being registered for research, <ul style="list-style-type: none"> ○ What Research procedures are being billed to the study? ○ Current study activity (budget) number? ○ Review process for research registration. 	
V. Other	
<input type="checkbox"/> All non-Children's hospital research staff must have a basic CHRMC hospital orientation and fill out appropriate forms before seeing study subjects. Please forward the name and contact information on all non-children's research staff to Pam Joy who will notify Sara Castro (HR). Once all background checks are complete, confidentiality papers signed, occupational health visit complete, human subjects/HIPAA training etc, they will get their badge and be able to see study subjects.	