

CHILDREN'S HOSPITAL AND REGIONAL MEDICAL CENTER
Seattle, Washington

OPERATING POLICIES / PROCEDURES

DEPARTMENT: Research Support Services

POLICY NUMBER: CTM-300

REPLACES: New

EFFECTIVE DATE: July 19, 2007

REVISION DATE: _____

POLICY TITLE: Clinical Research Staff Qualifications

POLICY: Children's is committed to assuring safe, quality care for clinical research study participants and to maintaining the highest standard of study conduct.

Clinical research study activities will be performed only by qualified, trained research staff at Children's. Research staff must meet the training and job requirements for their role. They will perform only those job functions for which they are specifically trained, licensed, certified and credentialed for at Children's. All direct patient care activities must be performed by licensed research staff in accordance with Children's clinical care policies, institutional practice and other guidelines.

GOAL: To clarify the qualifications and work responsibilities for Children's clinical research staff.

PROCEDURE:

300.1 Study Conduct

300.1.1 The Investigator is responsible for all aspects of conducting a clinical research study. Responsibilities include, but are not limited to, ensuring IRB and regulatory compliance, adherence to Good Clinical Practice, reporting of adverse events and protocol deviations, and ensuring fiscal compliance.

300.1.1.1 The Investigator may delegate specific tasks to qualified members of the research team. These individuals may include a sub-investigator, clinical research associate, or research coordinator.

300.1.1.2 The Investigator has direct responsibility for study related activities conducted by their research team.

300.1.1.3 Clinical research staff is responsible for conducting studies in accordance with all applicable laws, regulations, Good Clinical Practice standards and Children's clinical and research policies.

300.2 Qualifications of Research Staff

300.2.1 Staff performing activities for clinical research studies must be specifically designated as clinical research staff.

300.2.1.1 Designated research staff are defined as staff hired under a research position and work content description (WCD) or those who have research activities specifically listed as essential functions in their non-research WCD (if less than 20% effort dedicated to research).

300.2.1.1.1 Employees with more than 20% of their time delegated to research activities require a separate research position and WCD.

300.2.2. Research staff must be qualified and trained to perform the specific functions of their role. Specific qualifications are listed in the WCD for each position. For training requirements, refer to policy CTM-310.

300.2.3 Questions regarding research staff qualifications or responsibilities should be referred to Research Human Resources.

300.3 Scope of Research Staff Activities

300.3.1 Research staff will perform only those activities listed in their Work Content Description.

300.3.1.1 WCDs may be modified to expand research staff roles if determined to be appropriate by the Investigator, Children's supervisor and in accordance with Human Resources (HR) policy. Additional training, experience and/or credentialing may be required.

300.3.2 In accordance with Children's clinical care policies, research staff performing direct patient care activities must be licensed.

300.3.2.1 Licensed staff include, but are not limited to, physicians, registered nurses, nurse practitioners, physician assistants, medical assistants, respiratory therapists, and nutritionists.

300.3.3 For the purposes of this policy, clinical research activities will be classified into three main categories. These categories are administrative activities, interactive activities, and direct care activities. All qualified and trained clinical research staff may perform administrative and interactive activities. Only licensed research staff may perform direct care activities. Examples of common tasks for each category are listed below.

- 300.3.3.1 *Administrative activities* include, but are not limited to:
- Creating and organizing research documents (IRB, SAC, regulatory binders, source documents and case report forms),
 - Assisting in determining eligibility for studies,
 - Obtaining and organizing study supplies and equipment,
 - Organizing, compiling and documenting research data,
 - Coordinating and communicating with all individuals (research and clinical) involved with the study.
- 300.3.3.2 *Interactive activities* include, but are not limited to:
- Identifying, recruiting and consenting eligible research participants for minimal risk studies,
 - Administering questionnaires,
 - Conducting telephone follow-up,
 - Scheduling study visits,
 - Collecting study materials (diaries, unused medication),
 - Determining appropriate tests and scheduling appointments based on protocols,
 - Communicating study specific and non-medical information to participants,
 - Acting as central contact for the study.
- 300.3.3.3 *Direct care activities* may only be performed by licensed clinical research staff and include, but are not limited to:
- Taking heights/weights,
 - Taking vital signs,
 - Obtaining specimens directly from patients,
 - Performing phlebotomy and IV placement,
 - Documenting heights/weights, vital signs, pain assessments, medical history, including medications and allergies in Children's medical record,
 - Educating study participants regarding medical issues, such as drug information and care instructions,
 - Writing or activating orders including medications,
 - Managing medications including new, modifications or refill prescription functions.
- 300.3.3.3.1 Research staff that performs direct care activities must adhere to all Children's clinical care policies and institutional clinical care practices. Any direct care activities are under the authority of Children's clinical care management, even if those direct care activities are solely for research purposes.
- 300.3.4 Refer to specific research position WCD(s) for detailed descriptions of research staff roles.
- 300.3.5 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 member.

DEFINITIONS:

Administrative Activities

Organizational activities that are integral to the research study but do not involve interacting with research participants. Most commonly these activities involve creating and organizing hard copy and electronic documents.

Direct Care Activities

Direct Care Activities include those activities that involve physically interacting with a research participant to obtain clinical data, make a clinical judgment, or document data in Children's medical record. Participant questionnaires or surveys are not considered direct care activities.

Interactive Activities

Activities that involve interacting and communicating with research participants. These activities may involve recruiting and consenting eligible participants, administering questionnaires, and telephone follow up. They do not require physically interacting with the participant.

Principal Investigator (PI)

A Principal Investigator (PI) is an individual designated by the grantee to direct the project or activity being supported by the grant/contract. He or she is responsible for the scientific and technical direction of a project, the day-to-day management of the project or program, and is accountable to the grantee for the proper conduct of the project or activity.

Research Participant Care Activities:

Activities that involve directly interacting with a research subject to obtain data or make a clinical judgment regarding a patient. Examples of these activities include, but are not limited to; vital signs, height/weights, obtaining specimens, obtaining so anyone who actually touches a patient has had formal clinical training.

Research Staff (or Research Team Member)

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).

Sub-Investigator

Clinicians and members of the study team who assist the PI in conducting the study. Also known as Co-Investigators.

Work Content Description

Children's official document describing the knowledge, skills and abilities as well as the education and experience requirements for a specific position. It also provides a description of the role, the essential functions, and the criteria for performance evaluation.

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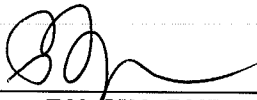
RELATED CHILDREN'S POLICIES:

- Certified Medical Assistants (CMAs) Role in Documentation and Ordering in Ambulatory Services
- General Medication Administration and Specific Guidelines for High Risk Medications
- Medication Ordering and Transcription
- RO-201: Research Project Funding Requirement and Research Staff Employment Provisions

Policy reviewed by Research HR, June 2007.

Submitting Office: **Office of Clinical Research**

Approved by:



Pam Joy, RN, MN, PNP
Director, Office of Clinical Research

July 5th 2007

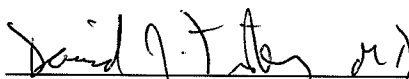
Date



Susan Heath, RN, MN, CNAA
Senior Vice President, Chief Nursing Officer

7-9-07

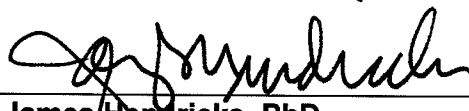
Date



David Fisher, MD
Senior Vice President and Chief Medical Officer

7/14/07

Date



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

7/19/07

Date