



KAISER PERMANENTE®

**Clinical Research Nurse Manager (Grade 47)
Job Family: Research & Development**

Requisition ID: RE.0801168	Internal Post Date: 05/24/2008	Internal Post Expiration: 05/23/2010
Public Department Description: Division of Research	Facility Name: Regional Office	Work Location: 2000 Broadway, Oakland 94612
Position Type: Full-Time Regular	Scheduled Hrs per Week: 40	Shift: Day
Working Hours (Start): See schedule below	Working Hours (End): See schedule below	Work Days: See schedule below
Job Code: 949161	Grade/Salary Range:	Employee Group: Salaried Employees
Division: Regional Offices	EEO Category: 1E - Managers	AAP Goal: Hispanic
Entity/Loc Code/Cost Center: 1.015.9773	Replacement? Addition	Replacement Name:
Hiring Manager: Maureen Fitzpatrick	ERAP: N	Recruiter: Chris Jones

Qualifications:

This position supports Kaiser Permanente's code of conduct and compliance by adhering to all laws and regulations, accreditation and Licensure requirements, and internal policies and procedures. Kaiser Permanente is proud to be an equal opportunity/affirmative action employer.

DEPARTMENT: DIVISION OF RESEARCH

SCHEDULE: Full-time Regular; 40 hours per week; Schedule days and times will vary depending on departmental need.

POSITION SUMMARY:

Directs, coordinates, leads, and facilitates multiple research trials, sites, and multi-disciplinary clinical research staff in the testing and evaluation of investigational drugs and vaccines. Works directly with the sponsors and investigators. Develops and maintains good clinical practice standards, budgets and staff development programs. Participates in the research contract acquisition process. Ensures compliance with organizational and government regulatory standards.

EDUCATION/LICENSE/CERTIFICATION: Bachelors degree in nursing or related health field required. Graduate of an accredited school of nursing. Current California RN license required. Current BCLS.

QUALIFICATIONS:

Significant experience (usually 5+ years) in a research/health care environment to include management and supervisory responsibility; the development of research procedures to support the research design/principles of a particular project; and in-patient and out-patient care experience.

Excellent project management, written and oral communications, and statistical analysis skills.

SKILLS TESTING: N/A

DUTIES:

Collaborates with principal investigators and sponsors in establishing, implementing and conducting clinical research trials which test the safety, efficacy and toxicity of experimental drugs, vaccines, and devices on KFHP members. Manages the operations of research units at multiple locations. Supervises research staff, assesses their needs, and identifies educational opportunities. Recruits and hires new clinical research staff. Develops training materials and takes responsibility for training of new hires. Directs and designs quality assurance programs for clinical trials. Collaborates in the management of research data. Implements quality assurance programs and develops strategies which improve the quality of research conducted and patient care. Develops and presents quality assurance training programs. Responsibilities for performance evaluations of the research staff. Counsels and disciplines staff members who are non-compliant with applicable policies, procedures, and standards. Manages and resolves human resource, employee, and department issues. Performs as a point person for decision-making and problem solving day to day operation of projects, including the resolution of technical problems and questions of research staff. Acts as patient advocate resolving patient care issues. Designs and evaluates processes to improve systems and patient outcomes across the continuum of care. Participates in design and development of overall clinical plans for the conduction of multiple clinical trials. Develops and implements protocol specific standard operating procedures. Determines and monitors budgets for the appropriate use of human and material resources. Monitors financial performance. Identifies and implements strategies to reduce cost and improve quality. Ensures compliance with KFHP, Nursing Practice Act, federal, state, local and other (The Joint Commission) regulatory requirements which govern the testing of investigational drugs and vaccines.

Consistently supports compliance and the Principles of Responsibility (Kaiser Permanente's Code of Conduct) by maintaining the privacy and confidentiality of information, protecting the assets of the organization, acting with ethics and integrity, reporting non-compliance, and adhering to applicable federal, state and local laws and regulations, accreditation and licenser requirements (if applicable), and Kaiser Permanente's policies and procedures.

Kaiser Permanente conducts compensation reviews of positions on a routine basis. At any time, Kaiser Permanente reserves the right to reevaluate and change job descriptions, or to change such positions from salaried to hourly pay status. Such changes are generally implemented only after notice is given to affected employees.

OTHER DUTIES:

Under the supervision of the DOR Clinical Comprehensive Research Unit (CCRU) Operations Manager and the CCRU Director:

Consult on the conduct and administration of all clinical research in the Region.

With oversight from CCRU Operations Manager and KPNC Compliance Director, assist with ensuring compliance with KPNC IRB Standard Operating Procedures (SOP) and document applications.

Adhere to Guideline for Good Clinical Practice (GCP), federal, state, and local regulations, and KP policies and procedures and communicate any concerns to the KPNC Compliance Director and CCRU Operations Manager.

Assist research sites in preparing for sponsor study start-up and monitoring visits.

Assist with the development of staffing plans for individual studies.

Assist the sites with developing source documents, databases, and other study record keeping materials.

Assist the sites with organizing the study environment to ensure that study materials are stored properly and that records and any other PHI is secured.

Train staff on packaging and shipping of protocol specimens to the Sponsor lab in accordance with IATA/DOT regulations and Sponsor shipping guidelines, if applicable.

As needed, train staff on how to abstract data from source documentation onto case report forms (paper or electronic) in a timely manner.

As needed, advise staff on resolution of data queries, data lock, study closeout, and archiving of study files.

Support the regulatory team in the maintenance and storage of critical documents required to be maintained and provided to the Sponsor during the conduct of the trial.

Assist CCRU Operations Manager with developing training for clinical research staff. Conduct on-site training at the medical facilities.

Independently develop/manage complex narrative and quantitative reports to meet informational requirements of administrative management and/or external parties (e.g., Sponsor, CRO) for critical financial, departmental, or operational analyses.

Participate with the CCRU Team to identify and prioritize the development of clinical trials' systems and infrastructure to maintain research quality and compliance of regulatory files at clinical trial sites.

Adhere to departmental policies and procedures to ensure confidentiality, privacy and security of clinical research interactions and participant information, and responsible use of operational research databases in compliance with KP policies.

Work with the Operations Manager and budget analyst to monitor study spending and implement corrective actions when necessary.