Clinical Research Coordinator 2

School of Medicine, Stanford, California, United States NEW

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The Stanford University Department of Orthopaedic Surgery is seeking a Clinical Research Coordinator II to manage and conduct clinical research for the Pediatrics division. Independently manage significant and key aspects of several large, national data registries and one industry-sponsored clinical trial, in addition to all aspects of one or more small research studies run by various medical students, fellows, and residents. This position coordinates moderately complex aspects of the clinical studies and works under close direction of the research program manager and faculty. The ideal candidate will serve as the primary point of contact for the study participants and be motivated to support a cohesive and mission driven team of faculty and staff that are advancing the field of Orthopaedic Surgery. To learn more about the research program in Pediatric Orthopaedics, please feel free to visit the following webpage: http://med.stanford.edu/pedsortho.html

Duties include:

- Oversee subject recruitment and study enrollment goals. Determine effective strategies for promoting/recruiting research participants and retaining participants in long-term clinical trials.
- Oversee data management for research projects. Develop and manage systems to organize, collect, report, and monitor data collection. Extract, analyze, and interpret data.
- Develop project schedules, targets, measurements, and accountabilities, as assigned. Lead team meetings and prepare/approve minutes.
- Formally supervise, train, and/or mentor new staff or students, as assigned, potentially including hiring, preparing or assisting with the preparation of performance evaluations, and performing related duties, in addition to instruction on project work.
- Audit operations, including laboratory procedures, to ensure compliance with applicable regulations; provide leadership in identifying and implementing corrective actions/processes. Monitor Institutional Review Board submissions, and respond to requests and questions.
- Collaborate with principal investigators and study sponsors, monitor and report serious adverse events, and resolve study queries.
- Provide leadership in determining, recommending, and implementing improvements to policies/processes; define best practices.

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- Develop study budget with staff and principal investigator, identifying standard of care versus study procedures. Track patient and study specific milestones, and invoice sponsors according to study contract.
- Ensure regulatory compliance. Regularly inspect study document to ensure ongoing regulatory compliance.
- Work with principal investigator to ensure Investigational New Drug applications are submitted to the FDA when applicable. Ensure Institutional Review Board renewals are completed.

* - Other duties may also be assigned

DESIRED QUALIFICATIONS:

- Bachelor’s Degree in biology, chemistry, public health or other health-related field.
- 2-3 years working in clinical research.
- Managerial Experience.
- Ability to work fast and efficiently within time constraints.
- Ability to work independently and comfortably with study participants.
- Prior data entry and management experience.

EDUCATION & EXPERIENCE (REQUIRED):

Bachelor's degree in a related field and two years of experience in clinical research, or an equivalent combination of education and relevant experience.

KNOWLEDGE, SKILLS AND ABILITIES (REQUIRED):

- Strong interpersonal skills
- Proficiency with Microsoft Office and database applications.
- Experience with research protocols and regulatory or governing bodies, which include HIPAA and FDA regulations, Institutional Review Board requirements, and Good Clinical Practices.
- Knowledge of medical terminology.

CERTIFICATIONS & LICENSES:

Society of Clinical Research Associates or Association of Clinical Research Professionals certification is preferred. May require a valid California Driver’s License.

PHYSICAL REQUIREMENTS*:

- Frequently stand, walk, twist, bend, stoop, squat and use fine light/fine grasping.
- Occasionally sit, reach above shoulders, perform desk based computer tasks, use a telephone and write by hand, lift, carry, push, and pull objects that weigh up to 40 pounds.
- Rarely kneel, crawl, climb ladders, grasp forcefully, sort and file paperwork or parts, rarely lift, carry, push, and pull objects that weigh 40 pounds or more.

* - Consistent with its obligations under the law, the University will provide reasonable accommodation to any employee with a disability who requires accommodation to perform the essential functions of his or her job.

WORKING CONDITIONS:

- Position may at times require the employee to work with or be in areas where hazardous materials and/or exposure to chemicals, blood, body fluid or tissues and risk of exposure to contagious diseases and infections.
- May require extended or unusual work hours based on research requirements and business needs.

WORK STANDARDS:

- Interpersonal Skills: Demonstrates the ability to work well with Stanford colleagues and clients and with external organizations.

- Promote Culture of Safety: Demonstrates commitment to personal responsibility and value for safety; communicates safety concerns; uses and promotes safe behaviors based on training and lessons learned.
- Subject to and expected to comply with all applicable University policies and procedures, including but not limited to the personnel policies and other policies found in the University's Administrative Guide, http://adminguide.stanford.edu.

Additional Information

- Schedule: Full-time
- Job Code: 4923
- Employee Status: Regular
- Grade: H
- Department URL: http://ortho.stanford.edu
- Requisition ID: 86404