East Bay Rheumatology
Medical Group, Inc.

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EBRMG CRC Job Description

Who we are and what we do:

A small but busy, familial outpatient practice located in San Leandro, CA; East Bay Rheumatology Medical Group conducts cutting-edge research, working with leading Pharmaceutical Companies. Our goal is to find new and improved medications and treatments that help patients with their autoimmune and rheumatologic conditions.

Who we are looking for:

A ***Clinical Research Coordinator*** to join our small (yet mighty) team and work in supporting safe and compliant clinical research while conducting cutting-edge research in Rheumatoid Arthritis, Lupus, Osteoarthritis other rheumatic and autoimmune diseases. We are seeking an individual who is eager to roll up their sleeves and is passionate about the community we serve.

What we offer:

Hands-on experience with close patient care and education through direct work with the PI and Sub-I, fair hours allowing work-life balance, competitive salary, 401k contribution annually, Dental, Vision, Medical.

Qualities and qualifications we seek:

- Someone who is passionate about their work and eager to take on new challenges.
- Someone who thrives in a small team/practice environment and brings tenacity to their work.
- Someone who communicates well and can work in partnership with colleagues.
- Someone with strong organizational skills and is detail-oriented
- Bachelor's degree in related field and 2 years of experience in clinical research, or an equivalent combination of education and relevant experience
- Computer skills (Windows, Word, Excel, Outlook and Electronic Data Capture “EDC”)
- Experience with research protocols and regulatory or governing bodies (e.g. HIPAA, FDA regulations, Institutional Review Board requirements, and Good Clinical Practices)
- Knowledge of medical terminology and understanding of laboratory procedures

Yor job duties will include:

- Working under the general supervision of a Research Manager and working directly with the PI and Sub-I
- Serving as a liaison between the physicians and the patients.
- Developing source documents.
- Facilitating daily clinical trial activities.
- Conducting Informed Consent: holding knowledge of the informed consent process, communicating clearly with potential study patients about study protocols and being able to accurately answer questions about the protocols
- Direct patient care (e.g. screening patients, scheduling and coordinating visits, taking vitals, communicating with patients between visits, etc.).
- Managing onboarding of new studies: handling regulatory paperwork, contracts and budgets
- Reviewing and comprehending study protocols (including inclusion/exclusion criteria), study proceedings and timelines, confidentiality and privacy protections.
- Attending sponsor prequalification visits, monitor visits and study termination visits.
- Investigational Product handling (e.g. dispensing drug, mixing drug, medication reconciliation and drug accountability, etc.).

- Reviewing and entering data per clinical trial protocols.
- Communicating with CRO's of each clinical trial and respond to data clarification requests in timely manner
- Handle regulatory documents (e.g. monitoring Institutional Review Board submissions and respond to requests/questions, handle new protocol submissions and renewals/revisions).
- Ensuring that PI and Sub-I's clinical trial and research-related activities are performed in accordance with federal regulation, as well as facility and sponsoring agency's policies and procedures.
- Assisting the PI and Sub I in development of materials and tools necessary to appropriately train individuals involved in the conduct of the study around issues related to (but not limited to) protocol requirements, schedule of visits, and execution of research plan.
- Maintaining accurate and detailed records and logs (including screening logs, drug accountability logs, protocol deviation logs, etc) as required by the study sponsors.
- Completing case report forms and extracting data from patient charts in a timely manner.
- Coordinating and facilitating monitoring and auditing visits.
- Notifying appropriate institution officials of external audits by IRB's, regulatory agencies, CRO's and sponsors.
- Collaborating with PPI and sponsor to respond to any audit findings and implement approved recommendations.
- Cooperating with facility and sponsoring agency's compliance and monitoring efforts related to human research participating protection and report instances of noncompliance to the appropriate compliance office.
- Completing documentation on each study visit that is used to track all study related activities so that time, effort and materials can be accounted for in real-time.
- Ensuring that all laboratory specimens processing, and shipment is done in timely manner.
- Establishing and organizing study files (regulatory binders, study specific source documents, patient binders, etc).
- Assisting PI in submission of accurate and timely closeout documents to applicable federal agencies and sponsoring agency in accordance with federal regulations and institutional policies and procedures.
- Arranging secure storage of study documents that will be maintained according to institutional policy or for the contracted length of time, whichever is longer.
- Promoting the ethical conduct of research by reporting good faith suspicions of misconduct in research.